DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR 1987

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

HOUSE OF REPRESENTATIVES

NINETY-NINTH CONGRESS

SECOND SESSION

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DEPARTMENT OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR 1987

WEDNESDAY, FEBRUARY 19, 1986.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

TECHNICAL BRIEFING

WITNESS

JOHN J. O'SHAUGHNESSY, ASSISTANT SECRETARY FOR MANAGEMENT AND BUDGET

Mr. NATCHER. We have before the committee at this time Mr. John O'Shaughnessy, the Assistant Secretary for Management and Budget.

You have appeared before our committee on a number of occasions, and it is a pleasure to have you back this morning.

At this time, we will be pleased to hear from you.

Mr. O'SHAUGHNESSY. Thank you very much. It is a pleasure to be back before the committee.

OPENING REMARKS

Mr. Chairman, I would like to use some charts to help us walk through the HHS briefing on the technical aspects of the HHS budget for fiscal year 1987.

[CLERK'S NOTE: The charts referred to are reprinted following Mr. O'Shaughnessy's remarks.]

Let me begin with two overview charts which depict the place of the HHS budget in the overall Federal budget and the breakdown on the HHS budget itself.

First of all, the HHS budget is very large and growing—at approximately 35 percent of the Federal budget for this fiscal year. You can see the breakout, comparing it to the Department of Defense and interest payments.

The HHS budget is 96 percent due to entitlement spending, and 4 percent due to discretionary programs.

GRAMM-RUDMAN-HOLLINGS EXEMPTIONS

Let me also note for the committee's awareness, under the provisions of the Gramm-Rudman-Hollings Act, approximately 72 percent of the HHS is exempt from any reduction at all—72 percent.

Mr. CONTE. Of the 4 percent?

Mr. O'Shaughnessy. No, of the total HHS budget, mainly due to the Social Security and Medicaid programs.

Mr. Conte. 72 percent excluded.

Mr. O'Shaughnessy. And 93 percent is either excluded or limited in the reductions which can be taken. The major program that is limited is Medicare.

In terms of the components of the HHS budget, you can see the very large share, 61 or 62 percent, which is dedicated to the Old Age Survivors and Disability Insurance Programs. That is broken down—approximately $191.8 billion for the Old Age and Survivors Insurance program, of which $1.8 billion is for administrative expenses, and $21.1 billion for the Disability Insurance program, of which $800 million is for administration.

Of the $70.2 billion for medicare, $49.8 billion is for Part A, the hospital insurance program, and $20.4 billion which is appropriated by this committee is for Part B expenses.

In a few minutes we will discuss the medicaid program—level-funded at $25 billion.

ENTITLEMENT PROGRAMS

Mr. Conte. Give us what the entitlements are.

Mr. O'Shaughnessy. The Social Services Block Grant is $2.7 billion, the Black Lung program, $1 billion; the Child Support Enforcement is $729 million, and the Foster Care and Adoption Assistance Program is $604 million.

In terms of the components of the HHS organization reviewed by this committee, and the amounts to be expended, comparing fiscal years 1985, 1986 and 1987, we see the Public Health Service—down approximately $140 million; the Health Care Financing Administration—up almost $2 billion; the Social Security Administration and the Refugee program—level-funded; Child Support Enforcement—up somewhat, and the Human Development Services—almost level, but down a bit; and Departmental Management, down somewhat.

We can go to the Public Health Service.

Mr. Pursell. Just a point of clarification, please: Your first page shows outlay numbers. Do you then switch to budget authority numbers?

Mr. O'Shaughnessy. These should be outlay numbers. The second table is outlays.

Mr. Pursell. The first page is outlays, and the second is outlays?

Mr. O'Shaughnessy. Yes, the other components are budget authority.

Mr. Pursell. Why do you switch to the budget authority?

Mr. O'Shaughnessy. For the Old Age and Survivors Insurance and the Medicare programs, revenue is counted as budget authority. So in the first two charts, where we focus on the overall expenditures of the Department, it is a more clear picture to look at outlays. In the social security accounting system. Revenues in social security are counted as budget authority.

PUBLIC HEALTH SERVICE REQUEST

In terms of the Public Health Service, let me go through the component organizations, and what changes are in the budget.

The total for the Public Health Service is $8.99 billion, of which $7.83 billion is considered by this subcommittee. This excludes $424 million for the Food and Drug Administration, and $722 million for the Indian Health Service.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

For the Health Resources and Services Administration, the total is $1.183 billion.

Mr. CONTE. Are those 1986 figures assuming rescissions?

Mr. O'SHAUGHNESSY. This assumes both the Gramm-Rudman-Hollings reductions and the rescissions—correct.

Mr. CONTE. You got any deferrals in there?

Mr. O'SHAUGHNESSY. I don't believe so.

We are reproposing the consolidation of the Primary Care Block Grant, which would include the Community Health Centers, migrant health, black lung clinics and family planning programs.

We are also proposing the elimination of the Health Professions Education program for which $207 million was appropriated in 1986, and the Health Planning program, for which $20.9 million was appropriated in 1986, prior to the Gramm-Rudman-Hollings reductions.

The Department is also assuming that user fees of $10 million will be collected for the qualification reviews of health maintenance organizations seeking Federal approval, and for the Hill-Burton loan applications.

CENTERS FOR DISEASE CONTROL

For the Centers for Disease Control, the request is $380 million, an increase of $13 million over 1986. The budget is essentially a current services funding level for CDC, with the following changes:

Funding is not being requested for the NIOSH training, TB grants ($5 million, in 1986) and demonstrations for diabetes control (which is another $5 million in 1986) or the prevention research centers ($1.5 million in 1986).

There is no funding requested for the vaccine stockpile. The Department has come before the subcommittee for the last few years, and asked for increments of $4 million to build a 26-week supply of vaccines.

Right now, the stockpile is at 16 weeks, and no further funding is requested for this year.

NATIONAL INSTITUTES OF HEALTH

The committee may wish to look at the National Institutes of Health in several aspects. One of the major considerations should be the number of grants that might be awarded.

Up until now, the Department has concentrated mainly on the number of new and competing grants—somewhere in the 5,000 to 6,000 range, as the annual political approach for determining how large the research program should be.

The analytical tool the Department is now using relates to the total number of grants to be awarded by the National Institutes of Health; over the next five years the total request is 18,000 grants per year.

Basically, that would entail reducing the number of new and competing grants down from the appropriated level of 6,100 fiscal year 1986, to 5,519, by way of a rescission request in fiscal year 1986, and then down to 5,150 in fiscal year 1987, and moving down to 5,050 for 1988, with basically a 5,000 new and competing grant policy after that.

The total level of grants reached a high of 18,357 overall in fiscal year 1985, and this budget would bring that down to 18,000 total grants over the next few years.

Other research mechanisms are essentially funded at the 1986 level of $1.8 billion in fiscal year 1987. There is also a proposal to reform the method of payment for indirect costs.

Right now, those indirect costs for research comprise three major elements: utilities and rent; a use charge; and administrative costs of several types.

The proposal to reduce the average amount funded for the administrative expenses from approximately 27 percent currently, to 26 percent in 1986 and 20 percent in 1987 would be implemented through a revision of OMB Circular A-21. A proposal to revise that Circular was sent out last week, and there is a 30-day comment period for all interested parties to comment.

ALCOHOL, DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION

For the Alcohol, Drug Abuse and Mental Health Administration, the budget request is $928 million request for 1987, an increase of $11 million. The analytical tool for sizing the program would change from the focus on new and competing grants to overall grants, and the total policy level which is proposed is 1,400, which is approximately the 1986 level.

The block grant would be $490 million in 1987, and this would bring the funding level back to the 1986 level prior to the sequester order related to the Gramm-Rudman-Hollings reductions, which is a 4.3-percent reduction in 1986.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

In the Office of the Assistant Secretary for Health, there is an increase of $41 million over the 1986 level. In addition to $10 million for FDA, the Department is requesting a single appropriation of $203 million for AIDS research. An AIDS Coordinator has been designated, Dr. Walter Dowdle from the CDC, and the research emphasis is on drug treatment development and vaccines.

The Department is requesting a rescission of $41 million in AIDS funding for fiscal year 1986.

There is an increase in funding for health services research and statistics of $8.5 million, which is related to a five-year effort on the so-called HANES research, and $5 million for retirement pay to be put in a contingency fund.

HEALTH CARE FINANCING ADMINISTRATION

Health Care Financing Administration—the major legislative proposals before this Committee would be in the Medicaid program. In that regard, the Department is seeking a reduction of $1.3 billion for medical assistance payments to States. $300 million would be put into a special fund for States having trouble with the transition to the new level of medical expenditures in medicaid for a net reduction of $1 billion.

There is also a proposal to eliminate special administrative matching rates having to do with such matters as ADP and that would total approximately $260 million.

Finally, there is an assumption in the budget that approximately $160 million would be collected for sanctions related to error rates that were above the permitted amounts for the fiscal years 1981 through 1985.

The payments to the trust funds match the amount required under current law.

In terms of the program management amount, there is a request for $920 million for the Medicare contractors in fiscal year 1986, and then $957 million in 1987.

Let me go through some thinking with regard to the Medicare contractor budget in 1986. The amount shown here is $920 million, $43.5 million below the appropriated amount of $963 million.

The Department is requesting either a rescission down to the $920 million. Assuming that the Gramm-Rudman-Hollings requirement of a 4.3-percent reduction would be upheld; should that be the case, the $963 million appropriation would be reduced to approximately $923 million, and a further recision of $2 million would be requested to bring it back to the President's proposal last year for $920 million in funding for fiscal year 1986.

A contingency of approximately $15 million for that program is assumed in all cases.

The State Certification Program is fundamentally level with regard to the overall amounts of surveys to be done. There is some increase, but it includes more surveys of hospitals and a few surveys of other institutions.

SOCIAL SECURITY ADMINISTRATION

In terms of the social security program, in the Supplemental Security Income program, this would be a program funded at the full amount under current law, including a cost-of-living increase of 3.7 percent, provided to 3.9 million beneficiaries.

There will be legislation proposed to improve the coordination of Federal benefits to some SSI recipients, but that is under development now, and the savings amount would be only approximately $34 million in the program.

There are a number of items with regard to the AFDC program that bear consideration. The amount shown in these numbers assumes passage of all the items related to legislative changes in that program.

They are the following: they would be a reform of the Workfare program, as it is called, which would entail the elimination of the

Work Incentive program, and the substitution of the so-called Workfare program.

There would be an end to parents' benefits when the child reaches the age of 16, to make the program comparable to the social security program, and there is also an assumption that $777 million would be collected as offsetting receipts in fiscal year 1987 related to errors that were above the allowed amounts by law for fiscal years 1981 through 1985.

In terms of the refugee program, if I may skip to that, the major changes having to do with proposed legislation involve limiting payments to States for refugees for a period of 18 months, as opposed to the current 36 months.

Also, there would be a proposal to consolidate all the AFDC and Medicaid payments for refugees into the refugee program, as opposed to carrying those changes in the programs themselves.

The low-income Home Energy Assistance program would be restored to $2.1 billion prior to the Gramm-Rudman-Hollings reductions. The black lung program reduction reflects a decrease in the eligible population with a very minor change of $1 million; the total decrease is $35 million.

HUMAN DEVELOPMENT AND COMMUNITY SERVICES PROGRAMS

For the Human Development and Community Services Programs, the Social Services Block Grant would be funded at the authorization level of $2.7 billion.

Community Services Program—the Administration is proposing to eliminate the block grant; we are proposing to eliminate this in fiscal year 1986;, the amount shown on the table reflects the amount that will have been spent in the program up through March 1st of 1986.

The Head Start program is level-funded, as are the Aging Services programs to levels prior to the Gramm-Rudman-Hollings reductions. There are proposals for reducing the amount of discretionary research in the elderly programs.

The Family Social Services program reflects an increase associated with both prior-year claims, and the Foster Care program. The Work Incentive program is proposed for elimination.

There is also a proposal to create a new block grant for Family Crisis and Protective Services, and this would involve consolidation of the Family Violence program, Child Abuse State Grants and Child Abuse Discretionary programs.

This chart shows the amounts being requested for Departmental Management, and there they reflect mainly changes having to do with staffing requirements, although there are funds requested for certain administrative initiatives.

FULL-TIME EQUIVALENTS (FTE)

This chart shows the full-time equivalent staffing levels that the Department is using for planning purposes for fiscal year 1987. The major component I would highlight is that related to the Social Security Administration's five-year program for reducing its FTE levels by 19,000. The Social Security Administration will be in the third year of that program.

I would like to underscore that there have been no unusual number of office closings, and no expectations of any unusual number of office closings in the United States in relationship to the reduction of full-time equivalent staff.

FISCAL YEAR 1986 PROPOSALS

Let me just spend a moment, if I might, on the fiscal year 1986 budget proposals, because there are a number of factors interacting here, and this is something that takes a few minutes on which I can elaborate.

Starting with the appropriations that have been enacted, the Department has had to look at three different sets of changes. First of all, there are the Section 515 funds that is, Section 515 of the Treasury appropriations having to do with consulting services in certain accounts. The reduction in the Department is for $8 million related to that provision.

Second, there is the sequester order related to the implementation of the Gramm-Rudman-Hollings reduction of 4.3 percent, which will be taken throughout the Department, dependent on special provisions applying to certain activities.

The committee has, I believe, an analysis of the Projects, Programs and Activities by which the Department has basically defined how those reductions are being taken throughout the Department.

I would say that consistent with the legislation, the Department has provided the broadest definition of those Projects, Programs and Activities in the allocation of these reductions through the Department.

In addition to that, the Department is proposing rescissions in fiscal year 1986, as shown by the numbers on the table. In the Public Health Service, the major rescissions have to do with Health Profession Education program, and the Health Planning program.

In the Human Development Community Services category, that $259 million the major component is for the Office of Community Services. The total reduction here is shown as $725 million for the proposed rescission, and the sequester order of $790 million.

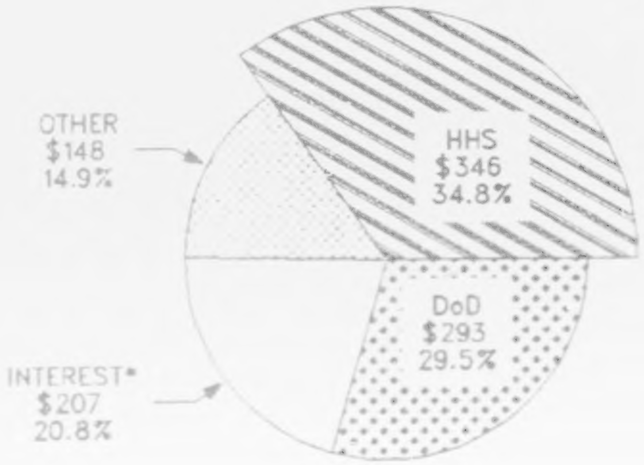
The total Gramm-Rudman-Hollings reduction in the Department, however, would be $1.035 billion in outlays.

The other reductions would be associated with the Medicare program, which is limited in fiscal year 1986 to a 1-percent reduction, and administrative areas of Social Security.

[The information follows:]

COMPOSITION OF FEDERAL BUDGET

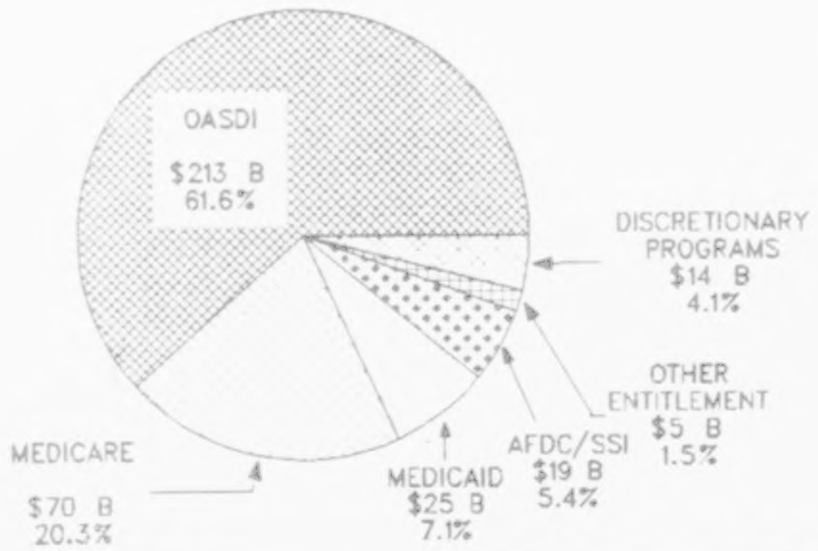
(Outlays)



TOTAL FY 1987 FEDERAL BUDGET=$994.0 BILLION

* INTEREST ON THE DEBT

DEPARTMENT OF HEALTH & HUMAN SERVICES
COMPOSITION OF FY 1987 PRESIDENT'S BUDGET
$345.6 BILLION



DEPARTMENT OF HEALTH & HUMAN SERVICES

PROGRAMS UNDER JURISDICTION OF LABOR/HHS SUBCOMMITTEE

(BA in millions)

	1985	1986	1987
PHS	$8,247	$7,975	$7,832
HCFA	40,703	43,379	45,150
SSA/REFUGEES	25,646	22,691	22,676
CHILD SUPPORT	635	586	729
HUMAN DEVELOPMENT/ COMMUNITY SERVICES	6,141	5,580	5,500
DEPARTMENTAL MANAGEMENT	214	180	158
TOTAL, HHS	$81,586	$80,391	$82,045

PUBLIC HEALTH SERVICE

(BA in millions)

	1985	1986	1987
HRSA	$1,533	$1,267	$1,183
CDC	382	367	380
NIH	5,089	5,060	4,936
ADAMHA	969	917	928
OASH	274	364	405
(AIDS)	(99)	(183)	(203)
TOTAL	$8,247	$7,975	$7,832

HEALTH CARE FINANCING ADMINISTRATION

	(BA in millions)		
	1985	1986	1987
MEDICAID	$21,855	$24,440	$24,708
(Legislative savings)	--	--	(-1,172)
PAYMENTS TO TRUST FUNDS	18,750	18,854	20,357
PROGRAM MANAGEMENT	98	85	85
(Program level)	(1,184)	(1,202)	(1,249)
(Medicare Contractors)	(873)	(920)	(957)
(Legislative savings)	--	--	(-5)
(Administration)	(222)	(206)	(215)
(State Certification)	(50)	(49)	(57)
(Research)	(34)	(22)	(19)
(ESRD Networks)	(5)	(5)	(1)
TOTAL	$40,703	$43,379	$45,150

SOCIAL SECURITY ADMINISTRATION/ REFUGEE PROGRAM

(BA in millions)

	1985	1986	1987
SSI	$9,442	$9,869	$10,535
(Legislative savings)	--	--	(-34)
AFDC	8,572	8,995	8,203
(Legislative savings)	--	---	(-237)
BLACK LUNG	1,036	998	963
LOW INCOME ENERGY	2,100	2,010	2,100
PAYMENTS TO TRUST FUNDS	4,013	497	501
ADMINISTRATION	(3,787)	(3,848)	(4,011)
REFUGEE PROGRAM	483	322	374
TOTAL	$25,646	$22,691	$22,676

HUMAN DEVELOPMENT AND COMMUNITY SERVICES

(BA in millions)

	1985	1986	1987
SOCIAL SERVICES	$2,725	$2,583	$2,700
COMMUNITY SERVICES	335	168	—
HEAD START	1,075	1,040	1,075
AGING PROGRAMS	702	660	689
FAMILY SOCIAL SERVICES	770	755	818
(Program level)	(735)	(760)	(818)
WORK INCENTIVES (WIN)	267	165	--
OTHER	267	209	213
TOTAL	$6,141	$5,580	$5,500

DEPARTMENTAL MANAGEMENT

(Obligations in millions)

	1985	1986	1987
DEPARTMENTAL MANAGEMENT	$141	$126	$136
INSPECTOR GENERAL	73	69	70
CIVIL RIGHTS	20	19	19
POLICY RESEARCH	10	6	5
TRUST FUND TRANSFER	–30	–40	–72
TOTAL, BUDGET AUTHORITY	$214	$180	$158

HHS EMPLOYMENT - FTE

	1985	1986	1987
PHS	23,669	22,838	22,038
HCFA	4,020	3,900	3,757
SSA/REFUGEES	79,055	77,430	74,461
CHILD SUPPORT	337	307	297
HUMAN DEVELOPMENT/ COMMUNITY SERVICES	1,244	1,182	1,141
DEPARTMENTAL MANAGEMENT	4,142	3,948	3,832
TOTAL, HHS (L/HHS)	112,467	109,605	105,526
NON L/HHS COMPONENTS	18,776	17,781	17,347
TOTAL, HHS	131,243	127,386	122,873

HHS 1986 BUDGET SUMMARY

(BA in millions)

	1986 ENACTED	SEC. 515 WITHHELD	SEQUESTER	PROPOSED RESCISSION	1986 REVISED REQUEST
PHS	$8,705	(-$6)	-$358	-$372	$7,975
HCFA	43,384	(-1)	-4	-1	43,379
SSA/REFUGEES	22,600	*	-143	-88	22,369
CHILD SUPPORT	619	*	-33	--	586
HUMAN DEVELOPMENT/ COMMUNITY SERVICES	5,911	(-1)	-244	-259	5,408
DEPARTMENTAL MANAGEMENT	193	*	-8	-5	180
TOTAL, HHS	$81,906	(-$8)	-$790	-$725	$80,391

* Less than $500,000.

Mr. NATCHER. We are glad to have you back before the committee.

ENTITLEMENT SAVINGS

Now, your budget includes large savings in entitlement programs through changes in basic laws, principally the Social Security Act. Some of these savings are assumed in your current proposal, and some are proposed for later transmittal.

Can you explain for the subcommittee why these programs are treated differently? Why are they different, Mr. O'Shaughnessy?

Mr. O'SHAUGHNESSY. They are basically in the Medicare program, major changes being proposed through two sets of mechanisms, and the first of what has to do with the use of regulatory authority available to the Secretary. The second is through legislation.

In terms of the proposals to be effected through legislation, the major elements there would involve the payment for hospital operating rates in fiscal year 1987, assumed to be limited to 2 percent in the budget, although that final decision is not yet made and cannot be made until the appropriate time under the law.

And second, reductions in the direct medical education program result in another $500 million, which is soon to be made through regulation, and there is an assumption that regulations will be used to change the reimbursement for capital expenditures, as well as for physician payments.

In terms of the legislative proposals, the major reductions have to do with the indirect medical education program, as well as the use of medicare as a secondary payor over age 69.

[The information follows:]

LEGISLATIVE PROPOSALS—LATER TRANSMITTAL

Four appropriations have legislative proposals for later transmittal:

	Pres. Budget	Amount Excluding Leg. Prop.
Health Care Financing Admin.:		
Program Management:		
Program level	($1,243)	($1,248)
Federal Funds	85	85
Payments to Health Care Trust Funds (Approp.)	19,058	20,357
Social Security Administration Supplemental Security Income	10,961	10,995
Child Support Enforcement	746	787

Mr. NATCHER. If your legislative proposals are not enacted, by the time the subcommittee marks up the bill, which amounts should we consider for accounts with large legislative savings proposed for later transmittal?

By way of example, should we consider the request for the payments to the Health Care Trust Funds account to be $20.357 billion, or $19.058 billion?

Mr. O'SHAUGHNESSY. The appropriate number would be $20.4 billion in that case.

CRITICAL REDUCTIONS—GRAMM-RUDMAN-HOLLINGS

Mr. NATCHER. The Gramm-Rudman-Hollings law provides for the sequestration of $790 million from Health and Human Services activities in 1986. Are there any of those cuts which have caused reductions in any of the Department's programs which are serious enough to justify a supplemental to restore any of these programs?

Mr. O'SHAUGHNESSY. Let me say that the consensus at all the meetings I have attended inside the Department is that there would not be any reduction below a critical minimum, so to speak, in the Department's budget as a result of the fiscal year 1986 reductions.

I am sure you will ask all major officials in the Department, but I am not aware of any major problems throughout the Department.

Mr. NATCHER. Do you expect to submit reprogramming requests to restore any of the Gramm-Rudman cuts?

Mr. O'SHAUGHNESSY. I do not anticipate that there will be any reprogrammings. Should the necessity arise, I will notify you immediately.

FOSTER CARE SUPPLEMENTAL

Mr. NATCHER. Your supplemental request for foster care and adoption assistance is proposed for later transmittal. When can we expect to receive this request?

Mr. O'SHAUGHNESSY. Sometime in April.

Mr. NATCHER. Are you aware of any other supplemental which may be proposed for activities in the Department of Health and Human Services?

Mr. O'SHAUGHNESSY. No, I am not, sir.

NEW SECRETARY—DR. OTIS BOWEN

Mr. NATCHER. Mr. O'Shaughnessy, I have had the opportunity to meet the new Secretary, Dr. Bowen, and I believe he is going to make a good Secretary. That is of great concern to us.

This is one of the Departments in the government that requires the services of a man of Dr. Bowen's qualifications.

I yield to you, Mr. Conte.

CLOSING OF SSA OFFICES

Mr. CONTE. Last year, during deliberations on the fiscal year 1986 bill, particularly in conference, we had quite a to-do over the level of employment and the issue of office closings with regard to the Social Security Administration.

As you recall, there was some restrictive language in the Senate bill which you strongly opposed. The Chairman and I received letters from you stating that SSA's personnel ceiling levels would be increased by up to 500 full-time equivalents, along with additional funds from the contingency.

Now I see that a deferral has been sent up to Congress on the additional $30 million we added to take care of the FTE situation.

Would you describe the impact of Gramm-Rudman on the Limitations on Administrative Expenses account, what effect this is having on employment, and why has this deferral been proposed, and what would be its effect on employment?

Mr. O'SHAUGHNESSY. Let me just take a moment to mention a few things.

PUBLIC SERVICE BY SSA OFFICES

In the letter that was sent to the committee, and I very much appreciate the hearing which it received by the Committee members, the statement was made that if there was an indication that public service performed by the Social Security Administration had deteriorated due to the inadequacy of the staffing levels, then up to 500 full-time equivalent positions would be requested, along with additional funds from the contingency amounts.

We have not received any indication that there has been any such deterioration occurring as of this point.

If the committee is aware of any such information, we would like to receive that, but none has been received so far by my office, and let me discuss why that may be the case.

When this six-year program was introduced, with a reduction of 17,000 full-time equivalents, it was generally perceived inside the Department that in the first two years the reduction could be taken really without any problems whatsoever, at least in the view of the managers of that program.

It was also felt, however, that in the absence of any major effort to manage the reductions over years three, four and five, there could be problems in terms of service.

The Social Security Administration, however, immediately put into effect a program for managing that reduction. Its current managers have, for the first time of which I am aware, introduced a personnel management system inside the Social Security Administration, gearing towards the reduction of the 17,000 full-time equivalent staff through attrition over a six-year period, and with no deterioration in service.

To the best of my knowledge, that program has been successful, and we are unaware of any deterioration in levels of service as of this point. In fact, the GAO has just issued a report indicating that the levels of service are perceived as quite good on the part of the beneficiaries of that program.

Secondly, with regard to the closing of offices, I believe there was some misunderstanding on that score in the past. The Department and the Social Security Administration embarked on an assessment of its ability to deliver services around the country, and looked at the numbers of offices, the size, et cetera. In that assessment, we were mainly concerned about small offices which were very close to each other, but still separate in a way that didn't provide the best service to individuals in various areas.

CONSOLIDATION OF OFFICES

And we felt that by closing small offices, bringing them together, if they were within very short distances of each other, it might actually improve the management of the program.

Some interpreted this normal review as a strategy for closing offices. It was at that time viewed as such, and in fact, the Department has ongoing nothing other than the normal review of the number of offices it has around the country.

As I have said before, there are no plans for any unusual closings of offices in the social security system at this time. What is usual and what is not? I don't have the numbers, and we are trying to get that.

I am assuming something on the order of 10, 12 or 20 have been closed every year for the last 40 years, but I may be wrong. We are trying to get that data, which would be available to the committee.

Mr. CONTE. In your letter you sent me at that time, you said the Office of Management and Budget had agreed that SSA's personnel ceilings could be increased by up to 500 full-time equivalent positions over requested levels in the 1986 President's budget, along with the additional funds from the contingency.

Are you saying now that they are not going to hire that 500?

Mr. O'SHAUGHNESSY. No, I would say that as the letter indicated, if the indications of service deteriorated, the Department would seek additional staffing.

As of this moment, I have not been apprised of any such indication of deterioration of service. If we were to receive that, we would request these additional staffing amounts as indicated in the letter.

LEGISLATIVE CHANGES

Mr. CONTE. How much of the budget is dependent upon enactment of legislative changes which would have to be acted upon by other committees?

Mr. O'SHAUGHNESSY. I will have to get that for the record, sir. There are other assumptions with regard to the collection of error rates which account for a sizable amount of money, $777 million in the AFDC program and $160 million in the medicaid program.

[The information follows:]

Legislative Proposals Included in Budget Request

Several accounts have legislative proposals included in the budget request. The proposals are listed below:

	Dollars in thousands
Health Care Financing Administration:	
Medicaid:	
Cap medical assistance payments	$ -882,000
State & local admin. cost freeze	-260,000
18 mo. all RCA/RMA refugee prog	-30,237
Total, Medicaid	-1,172,237
Program Management (Medicare Contractors)	
Contractor processing of RRB claims (Trust funds)	(—2,000)
Medicare contractor initiative (Trust funds)	(—2,800)
Total, Prog. Mgmt Trust Funds	(—4,800)
Social Security Administration:	
Assistance Payments (AFDC):	
Reform welfare administration	-15,000
Workfare benefits	-252,000
Workfare administration	+200,000
End parents' benefit/essential person limit	-101,000
Limit assist to minor mothers not living with parents	-20,000

	Dollars in thousands
18 mo. all RCA/RMA refugee prog	−48,742
Total, Assistance Payments	−236,742
Office of Refugee Resettlement: 18 mo. all RCA/RMA refugee prog	+78,979
Office of Human Development Services: Family Social Services Medicaid eligibility	−38,690
Total, Health & Human Services L/HHS	1,368,690

UNAUTHORIZED PROGRAMS

Mr. Conte. What programs proposed in your budget are unauthorized at the current time?

There must be some in here. Get that for the record.

[The information follows:]

Unauthorized Programs

Funding included in the fiscal year 1987 budget request for programs for which legislation has expired are:

	Dollars in thousands
Public Health Service:	
Health Services & Resources Admin. National Health Service Corps	$46,996
Office of the Asst. Secy. for Health Adolescent Family Life	14,722
Social Security Administration: Low Income Home Energy Assistance	2,100,000
Office of Refugee Resettlement	373,998
Office of Human Development Services	
Human Development Services	
Head Start, ACYF	1,075,059
Financial Assistance Grants, ANA	27,300
Subtotal, Health & Human Services, L/HHS	3,638,075
Public Health Service: Health Services & Resources Admin. Primary Care Block Grant [1]	565,100
Total, Health and Human Services, L/HHS	4,203,175

[1] In addition, legislation is being requested to consolidate the Community Health Centers, Black Lung Clinics, Migrant Health, and Family Planning programs into the Primary Care Block Grant. Of these programs only the Black Lung Clinics program has authorizing legislation.

The Health planning activities, for which there is no request in the fiscal year 1987 budget, were funded in fiscal year 1986, but lack legislation required to fund fiscal year 1987.

LEGISLATION ENACTED DURING LAST SESSION

Mr. Conte. What legislation was enacted last year that would have an impact on the HHS programs?

Mr. O'Shaughnessy. We will get that for the record, sir.

[The information follows:]

ENACTED LEGISLATION AFFECTING THE DEPARTMENT

During fiscal year 1985 the following legislation affecting the Department of Health and Human Services was enacted:

P.L. 99-15—Phase out the Federal Supplemental Compensation Program.
P.L. 99-46—Extend Saccharin Study and Labeling Act.
P.L. 99-80—Equal Access to Justice Act.
P.L. 99-87—Location and Recovery of Missing Children.
P.L. 99-91—Orphan Drug Amendments.
P.L. 99-92—Nurse Education Amendments.
P.L. 99-117—Health Services Amendments.
P.L. 99-129—Health Professions Training Assistance Act.
P.L. 99-155—Temporary Debt Limit.

P.L. 99-158—Health Research Extension Act.
P.L. 99-177—Balanced Budget and Emergency Deficit Control Act.
P.L. 99-190—Continuing Resolution.
P.L. 99-201—Medicare Hospital and Physician Payment Extension (to 3/14/86).
P.L. 99-221—Benefits for Former Employees Working for Indian Tribes.
P.L. 99-224—Equitable Waiver in the Compromise and Collection of Federal Claims.

In addition, two bills affecting Government employees were enacted:

P.L. 99-69—Flexible and Compressed Work Schedules for Federal Employees.
P.L. 99-109—Federal Employees Flexibility Schedule

In fiscal year 1986, one bill has been enacted that affects HHS programs:

P.L. 99-252—Comprehensive Smokeless Tobacco and Health Education Act.

RIFS OR FURLOUGHS

Mr. Conte. Will your Department, HHS, be taking any RIFs or furloughs?

Mr. O'Shaughnessy. I am not aware of any RIFs in fiscal year 1986, except for any associated with rescissions that have been requested such as the Health Professions Education and Health Planning programs, as well as the——

Mr. Conte. Gramm-Rudman, 4.3?

Mr. O'Shaughnessy. As of this point, I am unaware of any RIFs or furloughs in the Department connected with Gramm-Rudman-Hollings reductions. It is a possibility, particularly with regard to the Office of the Secretary, that there could be a furlough, in lieu of other kinds of changes, such as reduction in travel funds, et cetera.

That is still being studied at this point. In terms of the rest of the Department, I am unaware of any RIFs or furloughs.

Mr. Natcher. Mr. Stokes?

Mr. Stokes. Thank you, Mr. Chairman.

With regard to distribution of the proposed rescissions, who determined what programs would be selectd for rescissions and the amount of the rescissions, the Department or OMB?

Mr. O'Shaughnessy. All matters are done basically through agreement between the Department and the Office of Management and Budget. The Department submits its budget proposal to OMB. OMB, as in the past, passed back comments on that, and then there ensues a period of negotiations which is rather intense, and when everyone stops arguing, basically that is when a budget comes out.

So it is fair to say that is through agreement at that point.

Mr. Stokes. Is there a particular reason why over half of the proposed rescissions are in the Public Health Service?

Mr. O'Shaughnessy. These rescissions reflect the latest in a series of efforts to seek rescissions in certain areas. Many of the rescissions requested in fiscal year 1986 and reductions in 1987 have been requested for the past few years in the HHS budget.

Mr. Stokes. Tell us about the process through which the Department and the OMB arrived at those areas in which there are proposed rescissions.

How did you select the areas in which you proposed rescissions?

Mr. O'Shaughnessy. In terms of rescissions, and I will stand to be corrected by my staff, who actually trace these things more correctly, I am not aware that there has been any major controversy within the Department or between the Department and OMB with regard to the rescissions. This is simply because these items have been worked out over a period of years. The proposals for rescissions this year very much reflect the terminations that were proposed last year, programs such as the Health Professions Education and Health planning programs, proposed for rescission this year, termination was proposed last year, and I believe even the year before.

Health planning, is a similar situation. Last year the Department proposed termination of the program. The Community Services Block Grant, the WIN program—these are two programs the Department proposed to eliminate last year, and I believe even the year before that, and maybe even before that.

I know that they were requested. As a result, it is probably true that the rescissions proposed in the budget this year were even put forward by the Department in its initial request to OMB.

I don't recall any major level of controversy over these types of rescissions. There may be smaller programs over which there was some controversy, but there was no real controversy on rescissions.

RESCISSIONS PROPOSED FOR NIH

Mr. STOKES. You are proposing $63 million in rescissions for NIH, and of the $63 million, $9 million is the additional funding that Congress approved for the research centers in minority institutions, and the academic research enhancement awards.

Can you tell us why these two small initiatives were targeted for rescissions?

Mr. O'SHAUGHNESSY. In terms of the $63 million, let me take that in two pieces, in terms of the assistance for minority schools, the Department had proposed and the budget incorporates a request for $10 million, which it had provided last year for this program and that is continued in the Department's request for fiscal year 1987.

An additional $10 million was added to the Department's funding level last year, and the Department reviewed that and considered that $10 million, which would have brought the total to $20 million, was not something to request again for fiscal year 1987. It is proposed to stick to the original request of $10 million. Therefore the $10 million rescission would bring the level in 1986 consistent with 1987 rather than increasing and then decreasing the same activity.

In terms of the other $53 million,—in order to achieve the 18,000 objective without drastically reducing the number of competing research project grants in fiscal year 1987, the number of competing awards in fiscal year 1986 had to be reduced.

As a result, there was a scaling back of the new and competing grants in 1986 in order to accommodate more new and competing grants in 1987. The amount that was arrived at came to approximately $53 million for that amount of money.

Mr. NATCHER. Mr. Stokes?

Mr. STOKES. No further questions.

Mr. NATCHER. Mr. Pursell?

PHASE-ONE GRAMM-RUDMAN-HOLLINGS REDUCTIONS

Mr. PURSELL. I'd like to discuss the impact of Gramm-Rudman. You have translated your budget reductions already for phase one, a reduction of 4.3 percent. This fall, given whatever we do legislatively, that percentage may be much higher. I have heard the figure of 20 to 30 percent, at the maximum, and downward, depending on what we do to meet our targets for 1987.

Will you be making those same budget reductions within that discretionary part only? The law exempts entitlements, correct?

Mr. O'SHAUGHNESSY. Not all entitlements, such as, the Social Services Block Grant. It exempts a large percentage of the Health and Human Services budget, Social Security, Disability, Medicaid. Supplemental Survivors Income, ARDC——

Mr. PURSELL. For the fall, should sequestration take place, you will be looking at exactly the same programs as were reduced by percent 4.3 programmatically March 1st?

Mr. O'SHAUGHNESSY. Right. In the document that has been made available to the Committee, which outlined the Programs, Projects, and Activities which need to be defined under Gramm-Rudman-Hollings provisions, that has basically been set.

Any percentage decrease required by way of those provisions would be applied to all the programs contained in the Projects, Programs, and Activities list as already defined by the Department.

Mr. PURSELL. I am assuming that has been public, and the committee has those 4.3 percent reductions?

Mr. O'SHAUGHNESSY. I am sure you do. Yes, you do.

OTHER PROGRAMS GRAMM-RUDMAN-HOLLINGS REDUCTIONS

Mr. PURSELL. So there would be no other programs this fall that would be reduced should sequestration take place in addition to what we have had here?

Mr. O'SHAUGHNESSY. One major change, and that is the reduction in the Medicare program is limited to 1 percent of fiscal year 1986. It would increase to 2 percent maximum under 1987 and thereafter.

Mr. PURSELL. That's because it's in the law?

Mr. O'SHAUGHNESSY. That was in the law, and that is a change in the law. The maximum reduction in medicare in 1986 is 1 percent, and the maximum change thereafter is 2 percent.

Mr. PURSELL. No more?

Mr. O'SHAUGHNESSY. Right.

Mr. PURSELL. Okay.

CHANGES IN ENTITLEMENT PROGRAMS

In the entitlement programs over the years, have you, since you have been doing budget analysis, have you had a chance to look at the changes in entitlement programs? And, how about Medicare? We have an older population. Have you had a chance to analyze the rate of growth, whether we are slowing the rate of growth, or, because of an older population, are we just keeping up and dollar even, without any major gains or losses?

Mr. O'SHAUGHNESSY. There appears, obviously, to be a success in the medical area in terms of controlling health costs by basically reducing, on average, maybe a rate of 11 to 14 percent in the late seventies, to somewhere in the range of maybe 5 to 7 percent at this point.

As a result, all of the numbers show success in terms of slowing the rate of growth of the entitlements, particularly the Medicare program. In terms of Medicare and other health programs, it would be—I think it is fair to say, there seems to be some progress in terms of either the control of costs by States or in terms of buying more for the same amount of dollars throughout the States.

I say that simply based on the fact that each year, we seem to lower our estimates of Medicaid expenditures in the period of December, when we look at what the States proposed, and adjustments are made to those estimates, and reductions have been taken in the last couple of years, and those reductions have not really failed to be accurate.

Recently, there may have been some inaccuracy, and the costs were not as low as were estimated, but it wasn't very wrong, so there seems to be success.

CONTROLLING ENTITLEMENT COSTS

When the process began of trying to really control those costs, under this Administration in the early eighties, the health care inflation ran approximately 1.5 times, two times the rate of inflation in the economy.

If you look at the numbers right now, it is still 1.5 to two times the rate of inflation in the economy. On the one hand, you can say that is not a cause for concern, because inflation in the economy is fairly low, and seems to be controllable.

On the other hand, if that rate of inflation goes up for the economy as a whole, what does it do to health care inflation? That is an answer we don't have, and we would hope not to receive some bad news. So I would say yes, the numbers are down below our estimates.

We had done a backtrack on how much the Department had lowered its estimates of Medicare expenditures. Just in an 18-month period, it was between December of 1983 or January of 1984 and a year and a half later, we had lowered our estimates by about $10 billion in Medicare expenditures.

Mr. PURSELL. I would be interested in that, the changes in the rate of growth in the last 5- to 10-year period.

[The information follows:]

RATE OF GROWTH

The percentage growth of outlays for the Department and for Medicare are displayed below:

[In percent]

	HHS	Medicare
1977/1978	10.4	17.6
1978/1979	10.4	16.5

	HHS	Medicare
1979/1980	15.4	21.1
1980/1981	16.9	22.0
1981/1982	10.3	18.8
1982/1983	9.7	13.0
1983/1984	5.6	9.8
1984/1985	8.0	14.0
1985/1986	5.5	4.2
1986/1987	3.8	2.3

Mr. O'SHAUGHNESSY. Definitely, that has been a slowing of growth. Social security, that is geared to the cost of living changes in the economy, and those numbers have come down significantly from where they were.

Mr. PURSELL. Do you get significant savings or nominal savings in your entitlement programs as the unemployment figure declines? Does unemployment factor into the health programs?

Mr. O'SHAUGHNESSY. I would defer in the health programs because there were a series of major studies questioning the relationship between unemployment levels and health expenditures.

To the best of my knowledge, those studies indicated there was a lag in terms, or that there was a relationship, but it was lagged, so far behind as to be difficult to interpret.

In terms of other interactions between unemployment levels and the Department's proposals, or the Department's programs, I think it would mainly show up in the AFDC program.

Mr. PURSELL. Our caseloads in Michigan are declining. There does seem to be a direct relationship there.

Mr. O'SHAUGHNESSY. Yes.

Mr. PURSELL. There certainly is a relationship among the growth of the economy, unemployment, and entitlement programs.

Mr. O'SHAUGHNESSY. That is definitely the case. In terms of the exact specifics of the relationship in the health area, that may be very difficult to ascertain, although I know a lot of work has been done on that.

INCREASE IN MEDICARE POPULATION

Mr. PURSELL. Focusing on again: Medicare. Are we getting a significant number of additional people involved in medicare because of an older age population?

Mr. O'SHAUGHNESSY. It is a growing program, and 700,000 more people from 1986 to 1987.

Mr. PURSELL. Individuals, not families. Is that a trend over a period of time? That is not an unusual jump.

Mr. O'SHAUGHNESSY. No, it is not.

Mr. PURSELL. How about Medicaid?

Mr. O'SHAUGHNESSY. The 700,000 related to Medicaid. I am sorry, Medicare.

Ms. FOX. Medicare is up 600,000 between 1986 and 1987.

Mr. PURSELL. Thank you, Mr. Chairman.

Mr. NATCHER. In the House report last year, Mr. O'Shaughnessy, we directed that the Department submit a quarterly report on services to Social Security recipients.

When can we receive the first of these reports?

Mr. O'SHAUGHNESSY. It is being drafted right now. It should be up shortly.

Mr. NATCHER. Will we be able to receive the first of the reports before the Secretary appears?

Mr. O'SHAUGHNESSY. I am not sure about that. We will try. We will do our best, sir.

Mr. NATCHER. The committee will now recess until 2:00. Thank you very much, Mr. O'Shaughnessy.

Mr. O'SHAUGHNESSY. Thank you, sir.

WEDNESDAY, MARCH 5, 1986.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

WITNESSES

HONORABLE OTIS R. BOWEN, M.D., SECRETARY OF HEALTH AND HUMAN SERVICES

CHAIRMAN'S REMARKS

Mr. NATCHER. The committee will come to order.

At this time we have the new Secretary for the Department of Health and Human Services before the committee. Dr. Bowen, it is a pleasure to have you.

As I have said to you before, I look forward to working with you because I think you are well qualified for your assignment.

We have on this subcommittee, Mr. Secretary, on my right and left, members that are experienced members of the House, especially in the field of health and human services.

HISTORY OF APPROPRIATIONS

Mr. Secretary, down through the years from time to time we have had some problems with our bills. You might refer to it as the perils of Pauline. During the days from 1970 to 1976, our bills, including separate appropriation bills for education programs Mr. Secretary, were vetoed seven times.

Out of the seven vetoes, we overrode three times, we failed three, and one time was a pocket veto. For fiscal years 1978 and 1980, our bill did not clear Congress because of differences between the House and Senate over the issue of payment for abortions. In 1981, 1982 and 1983, the other side did not pass this bill. The bill was passed in the House. The Senate did not pass the bill. It had to be incorporated in continuing resolutions for those years.

President Reagan, as you know, has signed our bill for the last three years, and we appreciate it. This bill last year had to go under the continuing resolution and stayed for a short time. Mr. Conte, the ranking Minority member on the subcommittee and the ranking Minority on the full committee, along with the other members of the subcommittee and the chairman of the full committee, decided we would take this bill out from under the continuing resolution, bring the conference report to the House and the Senate, pass it and send it down to the President, and the President signed our bill, and Mr. Secretary, we appreciate it.

We worked hard on this bill. The hearings required from 14 to 18 weeks. We had many witnesses from the different departments, government witnesses, and then we had outside witnesses. But we say to them, Mr. Secretary, this is the bill that is closest to the heart of the people.

SECURITY OF NATION

I don't know of anyone in Indiana, your great state or in the state of Kentucky or Iowa or any other state, Mr. Secretary, who wants to place our country in a position from the standpoint of defense where the security of our country is in danger. I don't know any of those people, Mr. Secretary.

I know defense requires a lot of money, but in our bill we have all the programs in your department pertaining to health, cancer, heart and stroke research, all the clinics, the Center for Disease Control, AIDS; you name it, and it is in your department, Mr. Secretary, as you well know.

THE PEOPLE'S BILL

These are programs and projects that mean so much to our people, and we hope this year after our hearings that we can mark up a bill that you will like as the Secretary of Health and Human Services, that the other secretaries will like that come before us, and that the President will sign into law.

I wanted to make this preliminary statement to you to show you of our concern, and we will work to bring out a bill that the President will sign, and I am hoping as we go along that some of the obstacles that are in the road now, Mr. Secretary, can be removed.

Walking along the hall the first day of the hearings, I was just wondering what I would say to the members of the subcommittee as to how to approach this year's challenges. I thought, Mr. Secretary, I would say to them that each day we would start our hearings with a prayer. Maybe that would help us in this trying year.

But we hope to bring out a good bill, and Mr. Secretary, we are glad to have you. It is a pleasure to have you before our committee, and we will be pleased to hear from you.

Opening Statement

Secretary **Bowen**. Thank you very, very much, Mr. Chairman. I do want to thank you for your kind invitation to be here today. I also want to thank your distinguished colleagues.

I would like to share just a few brief remarks and request that my longer, written statement be made a part of the record.

As you know, it was only last December that I was honored with the confirmation as Secretary of Health and Human Services. In taking my oath of office, I was aware of the responsibilities that I was assuming, and I was also aware of the challenge.

At the State level, I have served as both legislator and governor, and at the Federal level, I have served on several advisory bodies, so I am aware of the problems that we face today. I am also aware that such problems are best solved in a spirit of mutual understanding, respect and cooperation. It is in that spirit that I took my oath of office, and it is in that same spirit that I am here today.

Our proposed departmental budget for fiscal year 1987 totals $345.6 billion. This is $12.7 billion more than our 1986 budget and

$30 billion more than the budget in 1985. Since 1981, the Department's budget has increased by $116.8 billion.

Our 1987 proposals total 34.8 percent of the Federal budget, which means that HHS is still the largest department in the Federal Government.

BUDGET REQUEST PRIORITIES

For the Department's programs considered by this subcommittee, our appropriations request for 1987 totals $82 billion. In fashioning this budget, our priorities were: balancing the budget by 1991 without a tax increase; containing health care costs while ensuring the quality of care; meeting our commitments to older Americans, the disabled and the truly less advantaged; and aiding families to enhance self-sufficiency by properly supporting the family as the vital nucleus of our society.

Included in these priorities are Social Security cost of living increases. For January of 1987, this increase is estimated at 3.7 percent.

Four years ago, double digit inflation and health care costs threatened to price that care out of the reach of many who needed it. We have come a long way in correcting that condition, but much is to be done if these costs are to be reduced still more.

In 1980, for example, Medicare and Medicaid outlays totalled $46 billion. By 1985, the cost of these programs had doubled, and if no action is taken, the cost of these programs will triple by 1991 to $150 billion.

Our 1987 proposals include a series of major regulatory and legislative changes to hold Medicare and Medicaid outlays in check without compromising the quality of care.

Our Medicare proposals are aimed at making health care affordable. They are expected to save $4.7 billion in 1987 and $54.5 billion over the next five years.

The principal initiatives include phasing hospital capital payments under the prospective payment system, revising graduate medical education payments, and restraining physicians and other provider payments while continuing to encourage competition in health care.

Our 1987 proposals would limit Federal Medicaid payments to $23.6 billion, and this would be $1 billion below the current estimate for fiscal year 1987. Each State's share for 1987 would be limited to a reasonable and fair increase over its 1987 expenditures, plus any amount that a state might receive from a special one-time hardship fund.

This fund is to help ease the transition. It will be made available to states encountering hardship despite bona fide cost control efforts.

For 1988 and beyond, fiscal year 1987 spending limits would be indexed to the medical care component of the Consumer Price Index.

To help states control their Medicaid spending, we will be proposing still greater program flexibility. This will enable States to target needed services to vulnerable groups to ensure the greatest payoff in preventing and resolving special health problems.

Other related measures we seek include legislation the Administration proposed recently to help states verify when recipients have third party health insurance coverage, thus avoiding the cost to Medicaid.

The Administration has also proposed AFDC job search, work experience and on-the-job training legislation that will help states reduce Medicaid costs.

CATASTROPHIC ILLNESS INSURANCE

In addition to these 1987 proposals, the President has called for an examination of how the private sector and Government can work together to address the problems of affordable insurance for those whose life savings would otherwise be threatened when catastrophic illness strikes.

We are enthusiastic about the President's charge to examine the entire question of catastrophic illness costs, including possible actions for both the private and the public sectors.

PUBLIC HEALTH SERVICE

Our 1987 request for the National Institutes of Health would establish a stable level of research grants. This level would be sustainable in future years when even greater deficit reduction targets would have to be met. Our total 1987 NIH request is $4.9 billion, and this will support 18,000 research project grants and 523 research centers. For the Alcohol, Drug Abuse and Mental Health Administration, our 1987 request will support 1,400 research project grants. Our 1987 request would also permit us to maintain efforts to prevent and control disease.

As the President has emphasized, AIDS remains the highest public health priority of our department. Under this priority, he has ordered a Surgeon General's report on the problem, and we have requested $213 million for AIDS research and education. Of this total, $203 million is requested for programs reviewed by this subcommittee, and $10 million is requested for the Food and Drug Administration.

The major programs of the Centers for Disease Control will be restored to their 1985 levels.

ASSISTANCE PROGRAMS

To further assist AFDC recipients to achieve self sufficiency, our 1987 proposals include work opportunity initiatives program. Through this new program, employable AFDC recipients would be directed into activities to help them find and keep jobs. These activities would include job search, community work experience, and on-the-job training.

Our 1987 proposals seek an additional increase of $56 million over the revised 1986 level for the foster care and adoption assistance programs, and we plan to restore other high priority family-related programs to their 1985 funding levels. These would include Head Start and nutrition programs, together with other services for older Americans.

Those who need our services are being served under our 1986 budget, and they will continue to be served under our 1987 proposals as well.

The nation's children will be served as well or better than before by our proposals. Our 1987 requests include $26.7 billion for 15 key children's programs. That is nearly $400 million more than the current estimate for 1986, and it is $1.9 billion more than 1985.

In 1987, Medicaid will serve 11.4 million children, and that is 75,000 than 1986 and more 700,000 over 1985.

Also in 1987, AFDC will continue to serve some 3.7 million families. Child support enforcement outlays will be increased 10 percent. This will increase collections from absent parents by more than $249 million in 1987 and it will bring total collections up to $3.3 billion.

PROGRAMS BENEFITING CHILDREN

Three child abuse and family violence programs will be consolidated into a family crisis and protective services grant to the States. It will provide states with broad authority to address this problem.

As I promised in my confirmation hearings, regulations implementing the family violence program will be issued this month.

With Head Start, we propose to restore the sequestration required by Gramm-Rudman-Hollings. The nearly 450,000 Head Start children we will serve in 1987 is nearly 20 percent more than those served in 1981.

Our efforts to improve child health care will continue. These efforts have already produced three encouraging results. A record number of children have been immunized against major childhood diseases. The infant mortality rate has been reduced to a record low of 10.4 per 1,000 live births. And life expectancy at birth has been increased to a record high of 74.6 years.

But we do not rest on these achievements because our obligations to our children are great. They are the nation's future.

OLDER AMERICANS

So too are our obligations to older Americans in need of our services. In 1987, we will serve about 5 million more meals to older Americans, both home delivered and congregate, than in 1985. And thanks to better management, we will do this at the same appropriations level.

While the overall national budget meets the 1987 deficit targets, funds for services under the Older Americans Act have been restored to the pre-Gramm-Rudman-Hollings level. Under the Older Americans Act, the 1985 budget provided $669 million for nutrition and support services. This was reduced to $640 million for 1986. It will be restored to the 1985 level in 1987.

FAMILIES

Of the many problems our department confronts, Mr. Chairman, none concerns me more gravely than the endangered status of many families. And while most families remain intact and resilient, others do not. The most tragic consequence of family breakdowns is the epidemic of teenage problems, teenage pregnancies, school dropouts, rampant drug use and the violence it spawns in our streets, homes, and schools. These are visible signs of family breakdowns.

The statistics that we collect tell a vivid story. Until a generation ago, the vast majority of all children lived in two-parent families. Twenty percent of all children born in the United States today are born out of wedlock. Often, they are born to mothers who, themselves, are still children. In fact, 54 percent of all children born to women 19 and under are born out of wedlock.

Young boys and girls must be brought to realize that teenage parenthood is a one-way ticket to poverty. We have no choice but to address this frightening condition. It tears deeply at our national fabric.

Over the past 20 years, Government has sought to prevent much of the damage which today we see about us. I do not question the good intentions behind the government's efforts. But intentions notwithstanding, we now must take a hard look at the empirical evidence of what has been wrought. If we would change that evidence, we must first change the nation's philosophy. If we are to fully address this problem, our schools, our churches, the media, and entertainment industry must assume their responsibility as well. They must do more to encourage a civilized code of conduct.

No nation in history has long endured by long ignoring this code. Teaching and upholding this code is a work of the families, supported by the institutions of the community. Government cannot do this job. It can only foster programs that support strong family life and sound community teamwork.

All of us who serve in Government need to take a fresh look at what Government can and cannot do to strengthen the family. And we need to acknowledge that Government has not always done an effective job in support of the family. This is why President Reagan has ordered a study of our social welfare system.

We need your thinking, in Congress, on these questions, too. As a one-time legislator myself, I know what public debate can do to stimulate public dialogue.

Mr. Chairman, that concludes my oral statement, and I will be pleased to respond to questions. And if I do not have a ready answer, I will be pleased to see that one is soon provided, either by one of my staff who are with me today or in writing.

[The prepared statement of Secretary Bowen follows:]

FOR RELEASE ONLY UPON DELIVERY

STATEMENT

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

DR. OTIS R. BOWEN

Secretary of Health and Human Services

Otis R. Bowen, M.D., was sworn in as secretary of health and human services Dec. 13, 1985, by U.S. District Court Judge Sarah Evans Barker. He was nominated by President Reagan Nov. 7, 1985, and confirmed by the Senate Dec. 12, 1985.

As head of the Department of Health and Human Services, Dr. Bowen oversees the federal agency responsible for the major health, welfare, food and drug safety, medical research and income security programs serving the American people.

A former two-term governor and member of the state House of Representatives in Indiana, Dr. Bowen came to HHS from the Indiana University School of Medicine in Indianapolis where he was serving as Lester D. Bibler professor of family medicine and director of undergraduate family practice education.

Dr. Bowen was born in Richland Center, Ind., Feb. 26, 1918. He received a bachelor's degree in chemistry from Indiana University in Bloomington in 1939 and his M.D. degree from the Indiana University School of Medicine in 1942. He interned at Memorial Hospital in South Bend, Ind., 1942-1943, and served in the Pacific Theatre during World War II as a member of the U.S. Army Medical Corps, 1943-1946.

Dr. Bowen was coroner in Marshall County, Ind., from 1952 to 1956. He served as a Republican member of the House of Representatives in Indiana in 1957, 1958 and 1961-1972, serving as Minority Leader, 1965-1966, and as Speaker for three terms, 1967-1972. He was governor of Indiana from 1973-1981.

He has served on a number of federal advisory bodies, including: chairman, Advisory Council on Social Security, 1982-1984; member, Presidential Advisory Committee on Federalism, 1981-1983; member of the Advisory Commission on Intergovernmental Relations, 1977-1979; President's Committee on Science and Technology, 1976-1977; and member of the Commission on Federal Paperwork, 1975-1977.

Other bodies he has served on include the Two Year Study on Nursing and Nursing Education, Institute of Medicine, National Academy of Sciences, 1981-1983; and the Education Commission of the States, 1973-1983 (chairman, 1978-1979).

Medical organizations in which Bowen holds memberships are the Marshall County Medical Society, Marion County Medical Society, Indiana State Medical Association, 13th District Medical Society, Indiana Academy of Family Physicians and the American Academy of Family Physicians.

Bowen has received honorary doctorates from 19 institutions of higher education including Indiana University, Indiana State University, Ball State University, University of Notre Dame and Purdue University.

Honors and awards received by Bowen include the merit award of the Indiana Public Health Association, its highest honor bestowed on an individual, for outstanding achievement in health; and the AMA's first Benjamin Rush Award for outstanding contribution by a physician in citizenship and public service.

He is a member of the Kiwanis Club, Phi Beta Pi, Alpha Omega Alpha, Delta Chi and Family Practice Club, IAFP.

Dr. Bowen has written extensively on health, welfare and educational matters.

He is married and has four children. He is residing in Alexandria, Va.

Mr. Chairman, Senator Proxmire, and Committee Members:

I am here today to present to you the fiscal year 1983 budget for the Department of Health and Human Services.

The priorities for health and human services we have embodied in this budget are based on two important assumptions: that spending must be tightly controlled to meet deficit reduction targets agreed upon by both the President and the Congress, and that essential benefits and services for the Nation's most vulnerable individuals and families must be maintained.

In balancing these priorities, we have been careful to meet our commitments to older Americans, the disabled, and other truly [illegible] self-sufficiency.

[illegible]

PUBLIC HEALTH SERVICE

For the programs of the Public Health Service (PHS) within [illegible]

[illegible]

[illegible]

[illegible]

b. Maternal and Child Health and Primary Care Block Grants

The budget includes $[illegible] million for the Maternal and Child Health and $[illegible] million for the Primary Care block grants. We continue to support the consolidation of the Community Health Centers, Family Planning, Migrant Health and Black Lung categorical grant programs into an expanded though simplified Primary Care block grant to enable States to meet local health service priorities.

c. Health Professions Education

In view of [illegible] increasing supplies of physicians and nurses, projected national surpluses in these occupational fields, and the improved distribution of health care practitioners to medically underserved areas, no funds are requested in [illegible] for the health professions and nursing education programs. These Federal subsidies were initiated [illegible] years ago to alleviate personnel shortages [illegible] at that time, [illegible] [illegible] phase out Federal support of these programs.

[illegible] provides $[illegible] million [illegible] [illegible] [illegible] percent [illegible]

d. Health Planning

Federal financial support [illegible] planning activities [illegible] [illegible] planning activities [illegible] [illegible].

Centers for Disease Control

The [illegible] budget continues to emphasize [illegible] and disease prevention in order to reduce the spread of disease, [illegible] illnesses, and [illegible] health.

For the principal programs of this agency, [illegible] a decrease of $[illegible] million over [illegible]. Highlights of this budget request follow:

o Immunization

In 198[illegible], $[illegible] million is requested for the immunization program, a net decrease of $[illegible] million below the [illegible] level. Within this level, funding for State grants and technical assistance will increase by $1 million above 1986. Through CDC leadership and provision of financial assistance to States, immunization levels of school-aged children have reached over [illegible] percent, and many childhood diseases, such as measles, mumps, rubella, tetanus and polio have been brought under control.

No funding is requested in 1987 for the Vaccine Stockpile. Through 1986, an average 15-week emergency reserve supply of all major childhood vaccines will have been accumulated in case of a disruption in domestic production. The Administration has transmitted to Congress legislation to eliminate punitive and limit non-economic damage awards against vaccine manufacturers to help ensure that these companies can obtain liability insurance, the major factor responsible for the temporary diphtheria-tetanus pertussis vaccine shortage of a year ago.

o Preventive Health Services Block Grant

In 1987, $[illegible] million is requested for the Preventive Health Services Block Grant to States. Funds from this block grant are provided to support State priorities in preventive health services in areas such as hypertension; emergency medical services; health risk reduction; rodent control; fluoridation; rape prevention; home health; and other comprehensive public health efforts.

National Institutes of Health

The 1987 request for the National Institutes of Health (NIH) is $[illegible] billion. This budget will continue support for basic health research that will be translated into future long-term improvements in medical care and the health of the American people.

Research will continue to be pursued during this period of rapid advancements in the life sciences in such priority areas as Alzheimer's disease, molecular genetics, immune system research, diagnostic brain imaging, and development of therapeutic agents and a vaccine against AIDS. In addition, studies on low birth weight of infants and preventive strategies for many adult disorders—stroke, epilepsy, and central nervous system trauma—will be enhanced.

o In 1987, $[illegible] billion is requested to fund 15,[illegible] research project grants. These research project grants will support individual research scientists who are the primary source of fundamental biomedical discoveries. Continued priority is given this key mechanism.

Increasing fiscal pressures throughout the Federal budget demand that a level of stability be achieved in project grants that will not "crowd" out other functions of resources for other research support mechanisms. Continuation of a policy level of [illegible] new and competing awards annually, resulting in a total of over 19,[illegible] grants in 1986, is a level we believe is not realistically sustainable over the next several years.

In addition to a stable policy for managing resources, NIH will devote greater cost consciousness in the review and funding of project proposals.

The budget request is sufficient to provide an estimated 2 percent increase in direct costs for research project grants. Payments for the allocated overhead portion of indirect costs to research grantees will be reduced by $65 million through a cap on the administrative components.

o $196 million is requested in 1987 to support an estimated 5,258 research trainees, a reduction of 700 from the 1986 estimated level of trainees.

o $447 million is included in the request to support 523 research centers, which focus research on such important topics as hypertension, arthritis, mental retardation, and Alzheimer disease.

o All other research mechanisms, such as contracts, disease control awards, and intramural research, are maintained in 1987 at essentially the 1986 level of $1.4 billion, with the exception of the phase-out of the Biomedical Research Support Grant and the Facilities Construction Grant programs. The request includes $10 million to continue efforts to stimulate health research at minority and other smaller schools which previously have received little or no NIH funding.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

A total of $922 million is requested in 1987, an increase of $17 million over the 1986 level, for the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) to support basic and behavioral research, training, and services to States. Included in this total is $490 million for the Alcohol, Drug Abuse and Mental Health Block Grant, $27 million more than the amount available in 1986.

o Similar to the NIH policy, priority in ADAMHA will be placed on funding 1,400 research project grants in 1987.

Emphasis will be placed on research in the neurosciences and addressing the major problem areas of schizophrenia and depression, continuing drug abuse studies on the "reinforcing" centers of the brain, the biological mechanisms involved in the susceptibility of alcoholism, and prevention efforts.

o No funds are requested for the Clinical Training Program, since overall shortages of personnel no longer exist.

o The budget request reflects a $4.6 million reduction in indirect cost payments to colleges and universities. Overhead expenses will be reduced through a cap on the administrative components of the indirect cost rate at 20 percent of direct costs.

St. Elizabeths Hospital

In 1987, the Federal subsidy to St. Elizabeths Hospital will be $30 million, $6 million less than in 1986, reflecting the fifth year of a planned ten-year phasedown of the direct Federal subsidy for the care of District residents. The budget reflects the assumption that this decrease will be offset primarily by increased payments from the District of Columbia. In 1984, legislation (P.L. 98-621) was enacted which provides for the direct transfer of the hospital to the District on October 1, 1987. By 1991, the District will pay the full cost of care for its residents.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

The 1987 request is $[illegible] million for programs in the Office of the Assistant Secretary for Health, an increase of $41 million over 1986. The following priority activities will be supported:

- $[illegible] million for health services research activities to: assess the adequacy, quality and cost of health care; examine and improve health care delivery methods; and test the cost-effectiveness of new and frequently used technologies.

- $[illegible] million for the National Center for Health Statistics to collect, analyze and disseminate nationwide data on illness, health resources, and vital statistics. Within the request, $[illegible] million will be used to continue preparations for the data collection phase of the next cycle of the National Health and Nutrition Examination Survey.

- $[illegible] million is included in the budget to foster the development of disease prevention and health promotion programs, with continued emphasis on bringing to the public a greater awareness of the hazards of smoking.

- Acquired Immune Deficiency Syndrome (AIDS)

  Over the past four years, this Department has supported a major research effort on AIDS to determine its cause and control its impact on the population, to develop the means for preventing this disease, and to improve the diagnosis and treatment for AIDS. In order to highlight, plan, and coordinate the total level of resources devoted to this top public health priority, the budget consolidates expenditures for AIDS activities in the Office of the Assistant Secretary for Health. Funds are also included in the Department of Agriculture appropriations bill which contains the Food and Drug Administration's (FDA) budget request. However, operational responsibility will continue to reside in the individual agencies involved (NIH, CDC, ADAMHA, and FDA).

  The budget authorizes allocation of AIDS funds among PHS agencies as scientific breakthroughs occur and new opportunities are identified. The Assistant Secretary for Health recently appointed an AIDS coordinator to monitor projects, identify gaps in activities, and make decisions that keep these efforts on track.

Over 16,500 cases of AIDS in the U.S. have been reported to the Centers for Disease Control since 1981. Extraordinary progress has been made in a relatively short time in understanding this new and devastating disease, including identification of the causative HTLV-III virus; enhancing the protection of the blood supply for the general public and especially for hemophiliacs; initiating clinical studies of promising therapeutic drugs; and developing public health guidelines for health care workers, schools, blood collection centers and others. To continue this effort, $213 million is requested in 1987 to combat AIDS. This includes $10 million requested for FDA.

HEALTH CARE FINANCING ADMINISTRATION

The total 1987 HCFA budget request for Medicare, Medicaid and related programs includes outlays of $[illegible] billion, an increase of $1.6 billion, or 2 percent, over the current estimate for 1986. Approximately [illegible] million beneficiaries will be served through the Medicare and Medicaid programs in 1987. This is a responsible budget designed to make health care more affordable.

This budget reflects the Administration's continued commitment to constrain rising Federal health care expenditures while meeting the health needs of the elderly, disabled, and poor. Although the rate of inflation in health care costs has declined during the past few years, these costs are still growing at almost twice the rate of general inflation. To moderate these cost increases, the budget request includes a number of legislative and regulatory proposals designed to slow the rate of growth in program expenditures. These proposals are expected to save the Medicare and Medicaid programs approximately $[illegible].4 billion in 1987.

For HCFA programs which require appropriations action -- primarily Medicaid and a portion of the Medicare program — we are requesting appropriations of $[illegible] billion in 1987.

MEDICAID

Medicaid appropriations of $[illegible] billion are projected for 1987. This includes $6.5 billion already provided in advance appropriations for the first quarter of 1987. In addition, $7.1 billion is requested for the first quarter of 1988. The request is based on November 1985 States' estimates and includes the impact of proposed regulatory and legislative savings of $1.4 billion.

The Administration's legislative and regulatory proposals for Medicaid are designed as incentives for States to moderate program growth and improve the efficiency of program operations. Specifically, these proposals would limit Federal expenditures for medical assistance payments to $[illegible] billion in 1987, while at the same time give States greater flexibility to design and operate their medical assistance programs. A one-time, hardship pool of $300 million would be available to assist States which, despite aggressive efforts to control costs, incur expenses above their limit.

In addition, we are proposing to eliminate all special matching rates for State and local Medicaid administrative costs and to reduce matching for excessively high administrative costs. This proposal, which would save $260 million in 1987, would eliminate special subsidies which have outlived their purpose and would also provide incentives for States with high administrative costs to achieve efficiencies. Related proposals will also be advanced for the AFDC and food stamp programs, and for child support enforcement in relation to elimination of special subsidies.

PAYMENTS TO HEALTH CARE TRUST FUNDS

A total of $[illegible] billion is requested for the Payments to the Health Care Trust Funds appropriation, an increase of $[illegible] billion above 1986. This amount reflects certain general revenue payments to Medicare, the largest being the Federal share of premiums for individuals enrolled in the Medicare Supplementary Medical Insurance (SMI) program (Medicare Part B). The growth in the Federal payment for the Part B program is primarily a result of rising program costs and increased utilization of physician and outpatient services. The appropriation request represents approximately [illegible] percent of total Part B program costs. Enactment of FY 1987 Medicare legislative proposals would reduce Payments to Health Care Trust Funds by a total of $[illegible] billion.

PROGRAM MANAGEMENT

The 1987 budget request includes $[illegible] million in appropriations and $1,[illegible] million in trust fund transfer authority to administer the Medicare and Medicaid programs. Highlights of the Program Management appropriation include:

o Medicare Contractors

A total of $[illegible] million is requested, an increase of $[illegible] million above 1986. In addition, we are requesting a $[illegible] million contingency fund, $[illegible] million more than 1986, for unanticipated workloads. Approximately [illegible] percent of the budget request for the Medicare contractors, or $[illegible] million, is allocated to claims-processing services. The remainder of the request will be used largely to assure the quality and appropriateness of health services provided to beneficiaries.

o State Survey and Certification

The $[illegible] million request, an increase of $[illegible] million above 1986, supports onsite surveys of approximately two-thirds of the facilities participating in Medicare. This level will provide annual inspections of all skilled nursing facilities and reflects the Department's continuing commitment to protect the health and safety of Medicare beneficiaries.

o Administrative Costs

A total of $[illegible] million is requested for Federal administrative costs, $[illegible] million more than in 1986. The

1987 request will support 3,757 FTEs, a reduction of 143 FTEs from 1986, accomplished through attrition and streamlining administrative processes and requirements.

- Research

  A program level of $19 million is requested for the research, demonstrations, and evaluation programs in 1987. Priorities will include refinement of the hospital prospective payment system, testing feasibility of capitated systems, and development and testing of alternative payment systems for skilled nursing facilities.

SOCIAL SECURITY ADMINISTRATION

The fiscal year 1987 budget for the Social Security Administration's (SSA) income security programs for the aged, disabled and poor totals $[illegible] billion in outlays financed through both trust funds and general fund appropriations. These programs, which constitute about [illegible] percent of 1987 budget outlays, will provide benefits to over [illegible] million people in 1987.

For programs subject to appropriations, we are requesting $27.5 billion for 1987, including previously appropriated advances of $[illegible] billion. Advances of $[illegible] billion for the first quarter of 1988 are also requested. The appropriations request by program is as follows:

SUPPLEMENTAL SECURITY INCOME (SSI)

The 1987 appropriations request for the Supplemental Security Income program is $[illegible] billion, including a previously appropriated advance of $[illegible] billion. For the first quarter of FY 1988, an advance appropriation of $[illegible] billion is requested. Federal benefit payments under this program will provide assistance to an average of 3.9 million recipients each month.

The 1987 budget request supports the Administration's commitment to a cost-of-living increase of 3.7 percent payable in January 1987 and a projected increase in the blind and disabled population.

AID TO FAMILIES WITH DEPENDENT CHILDREN (AFDC)

Total appropriations of $[illegible] billion have been requested for Assistance Payments for 1987, of which $[illegible] billion has already been provided as an advance appropriation. Also, $2.5 billion is requested in advance for the first quarter of 1988. These funds will provide assistance to an average of 3.7 million families each month.

The request includes several legislative proposals, three of which continue proposals previously made in this program. They are intended to ensure that assistance is provided only to those who are in need and who are not in a position to provide for themselves, and that strong work requirements exist for all able-bodied applicants and recipients. In 1987, these legislative proposals are estimated to result in net AFDC savings of $[illegible] million.

REFUGEE AND ENTRANT ASSISTANCE PROGRAM

In 1987, the budget request for Refugee and Entrant Assistance programs totals $[illegible] million in budget authority. This represents an increase of $[illegible] million above the level of funds available in 1986, but includes $[illegible] million of costs associated with new legislation previously funded from other accounts.

Legislation will be proposed to reduce welfare dependency among refugees, which is currently too high. The proposal would finance all refugee cash and medical assistance through this account under program rules more tailored to refugees' circumstances. This will give States more flexibility to provide job services, wage subsidies, and other employment services than is possible under current AFDC rules. The proposal would not affect the availability of [illegible] of benefits, only the financing arrangements. This change would result in a $[illegible] million increase in funding for Refugee and Entrant Assistance that would be offset entirely by reductions in the AFDC and Medicaid programs. Another component of the proposed legislation would, for 12 months, [illegible] full payment for [illegible] refugees. After the initial 12 months, refugees would receive aid on the same basis as other residents. This proposal saves $[illegible] million, compared to the cost of the current [illegible] period of [illegible] for the [illegible], [illegible] million [illegible].

In view of the [illegible] and very [illegible] welfare rates in recent years, the [illegible] of assistance programs.

[illegible] Programs:

[illegible] programs, [illegible] the [illegible] Social Security Trust Funds, [illegible] [illegible] benefits [illegible].

[illegible]

The [illegible] programs, [illegible], and [illegible] programs, Federal health insurance [illegible], and the Supplemental Security Income program.

In 1987, we are requesting [illegible] of $[illegible] million, [illegible]. The [illegible] from $[illegible] million to $[illegible] million. This will provide [illegible] with the [illegible] associated with the [illegible] of [illegible] legislation and [illegible] the [illegible] of [illegible]:

SSA will continue progress on its Systems Modernization Plan which is replacing SSA's outdated system of hardware, software, and storage capacity with one that is modern, efficient and reliable. To date, software and systems upgrades have reduced processing times and error rates, and improved SSA's service to the public. Productivity and service improvements are expected to continue at an even greater pace over the next few years.

OFFICE OF CHILD SUPPORT ENFORCEMENT

Vigorous implementation of changes made by the Child Support Enforcement Amendments of 1984 will continue to be a major priority in 1987. Total 1987 appropriations requested for the Office of Child Support Enforcement are $[illegible] million, including an advance appropriation of $171 million. This represents an increase of $[illegible] million over 1986. We are also requesting an advance appropriation for the first quarter of 1988 of $167 million. We estimate that child support collections will have more than doubled since 1982, from almost $1.[illegible] billion to almost $[illegible] billion in 1987, an increase of [illegible] percent or $[illegible] million compared to 1986.

OFFICE OF HUMAN DEVELOPMENT SERVICES AND OFFICE OF COMMUNITY SERVICES

We are requesting $[illegible] billion in appropriations for programs administered by these offices in 1987.

The budget continues the policies of this Administration to support social services and related programs which promote self-sufficiency among program recipients, while focusing Federal resources on the most effective and efficient programs. In sum, the 1987 budget will increase funding for Foster Care and Adoption Assistance; maintain most other service programs at current levels; reduce funds at selected research, training, and discretionary grants; and eliminate funding for the Community Services Block Grant and the Work Incentives Program.

BLOCK GRANTS

The 1987 budget request for the Social Services Block Grant is at the full authorization level of $[illegible] billion. No funding is requested for the Community Services Block Grant. Instead, the Department proposes that States use other sources of funding, including the Social Services Block Grant, to support those Community Services activities which are of the highest priority and most effective.

HEAD START

A total of $[illegible] million is requested for the Head Start program, an increase of $[illegible] million over 1986. This program provides comprehensive support services and early childhood development for poor and handicapped children up to age [illegible]. This level will support services to over [illegible] children, the same number as in 1986. Of the total enrollment, at least [illegible] percent will be handicapped.

FAMILY CRISIS AND PROTECTIVE SERVICES

The 1987 budget contains $36.5 million for a consolidated Family Crisis and Protective Services Grant Program. By combining three existing programs which address child abuse and family violence, this new grant will give States greater latitude in preventing, identifying, and treating all forms of abuse.

AGING PROGRAM

The 1987 budget includes a total of $[illegible] million for Aging programs.

Within this total, $[illegible] million is requested for activities under Title III of the Older Americans Act, the same level as provided in 1985 and an increase of $[illegible] million over 1986. These activities include supportive services and centers, the nutrition programs of congregate and home-delivered meals, and State agency administration.

The budget request also provides $[illegible] million for grants to Indian Tribes, restoring the amount sequestered by the Balanced Budget Act of 1985. This level will provide approximately 13[illegible] grants, serving over [illegible] older Indians.

DEVELOPMENTAL DISABILITIES

A total of $[illegible] million is requested for activities to develop and expand services for persons with developmental disabilities, the same level provided in 1986. Past employment efforts have been quite successful: in 1985 the Administration on Developmental Disabilities placed [illegible] persons with developmental disabilities in competitive employment. The 1987 level of funding will provide continued support for the Administration's effort to increase private sector employment opportunities for developmentally disabled individuals.

FAMILY SOCIAL SERVICES

The 1987 budget requests a total of $[illegible] million for programs to keep families together or to support other appropriate living arrangements when reunification of children and families is not possible. The amount requested is an increase of $[illegible] million over the previous level for 1986. The request continues support for legislation introduced as part of the 1986 budget which would: remove barriers to Medicaid coverage for children with special needs adopted under the Adoption Assistance program; modify requirements for Foster Care financing; and create incentives for States to reduce the duration of children's stays in Foster Care services.

The $[illegible] million requested includes $[illegible] million for Foster Care, $[illegible] million for Adoption Assistance, $[illegible] million for Child Welfare Services, $9 million for Child Welfare Training, and a total of $[illegible] million for Child Welfare Research and Demonstrations, Adoption Opportunities and Social Services Research activities.

WORK INCENTIVES

In 1987, no funds are requested for the Work Incentives (WIN) program because, as studies by the General Accounting Office and others have demonstrated, this program has not been effective in providing training or work experience to the AFDC recipients who need it the most. Instead, the budget continues to advocate legislation introduced last year which requires job search and work activities for AFDC recipients in all States, while giving States flexibility in the design of their specific work programs. These proposals build on legislation of the past five years which have given States powerful alternatives to the WIN program: community work experience, job search, and grant diversion. Under our proposal, States would have the flexibility to continue to further develop innovative work initiatives (now funded with WIN monies), such as those in place in California and Massachusetts, and to go beyond these programs to explore other approaches suited to the needs of their AFDC recipients.

DEPARTMENTAL MANAGEMENT

The 1987 budget also includes a [illegible] program level for activities under the Departmental Management appropriation. Departmental Management activities include the Office of the Secretary, the Office of Inspector General, the Office for Civil Rights and the Policy Research program.

For 1987, the budget proposes to [illegible] in the Office of the Secretary [illegible] Management through management improvements. An [illegible] decrease of 84 full-time permanent (FTP) staff will be met through attrition [illegible] practices.

In our Office of the Inspector General, we will target audit and investigative efforts on the large-dollar programs which provide the greatest potential for fraud, waste, and abuse savings and recoveries. [illegible] of the levels achieved during the past two years.

This budget demonstrates our commitment to ensure civil rights compliance among the Department's federally-assisted programs and activities. The 1987 Civil Rights program request will allow the Office for Civil Rights to continue its comprehensive compliance program which includes [illegible] compliance and outreach, review of [illegible], and prompt investigation of complaints of discrimination.

The $5 million requested for Policy Research in 1987 will continue funding [illegible] to the Department [illegible] flexible research capacity for work on issues of national policy significance in the health, income maintenance, and social services fields.

PROPOSED FISCAL YEAR 1986 RESCISSIONS

The 1987 budget proposes to rescind $724 million in 1986 budget authority for programs reviewed by this Subcommittee. In general, these proposals seek early elimination of programs previously identified as unnecessary or ineffective or initiate reductions in the second half of 1986 as a means of moderating reductions that would otherwise be required in 1987 under the President's budget. Major proposals include:

- o $[illegible] million for elimination of funding for the Community Services Block Grant in the second half of 1986.

- o $104 million for termination of support for Health Professions Education and Health Planning.

- o $[illegible] million in funding for the National Institutes of Health and the Alcohol, Drug Abuse and Mental Health Administration to provide a necessary transition to a stable level of 6,000 project grants in 1987.

- o $88 million for Refugee and Entrant Assistance to reduce excessive spending on activities that were helpful in 1980 when the influx of refugees was very large and immediate but which are no longer necessary now that the flow of refugees is much smaller and relatively stable.

- o $40 million for phase-out of the Work Incentives program in 1986 as a prelude to legislation for a new Work Opportunities program under AFDC in 1987.

EFFECT OF THE BALANCED BUDGET ACT ON HHS PROGRAMS IN 1986

FY 1986 budget estimates include the effect of the mandatory sequestering provisions of the Balanced Budget Act.

These provisions require a total reduction in Federal outlays of $11.7 billion, of which $5.85 billion is to come from non-defense spending including selected HHS programs. Because more than 70 percent of HHS outlays are totally exempt from reductions and other programs are subject to special rules, sequestering of HHS budgetary resources in 1986 results in outlay reductions of $791 million for programs under the jurisdiction of this Subcommittee as follows:

- o $47 million from other programs subject to special rules such as Child Support Enforcement, Community and Migrant Health Centers, Foster Care, and Adoption Assistance.

- o $744 million from a 4.3 percent across-the-board reduction for all programs not otherwise subject to special treatment.

- o No reductions are included for benefit or vendor payments from the exempt entitlement programs: Supplemental Security Income, Aid to Families with

Dependent Children, and Medicaid. However, the spending authority associated with the Federal cost of administering these programs is subject to sequestering of 4.3 percent.

Mr. Chairman, in partnership with the Congress, this Administration has restored the faith of the American people in the future and in our ability to solve the major issues of the day. The policies of the past five years have succeeded in ushering in a period of strong economic growth that has benefitted all Americans. Together, we have preserved the Social Security Trust Funds from insolvency so that young and elderly Americans alike can now look with confidence to their retirement years. Health care costs have also been restrained through the introduction of a prospective payment system, though more needs to be done if we are to have quality health care at an affordable price.

We can be proud of these accomplishments, but we must now face the very difficult task of reducing Federal spending and the Federal deficit in order to preserve the gains we have already made. I look forward to working with the Committee to meet this goal.

That concludes my remarks, Mr. Chairman, and I would be happy to answer your questions at this time.

PARTICIPATION IN FORMULATION OF BUDGET REQUEST

Mr. NATCHER. Thank you, Mr. Secretary.

Mr. Secretary, you have only been in office now a short time. How much input did you have in the development of your 1987 budget? We understand that the Office of Management and Budget had just issued its initial decisions as you were arriving at the Department. Mr. Secretary, I was glad to see that you were appealing some of them.

Go on ahead now and tell us what inputs you had in your 1987 budget.

Secretary BOWEN. Sir, the day I was sworn in, the passback came to my office. I barely knew what a passback was, but I soon got initiated into the process! [Laughter.]

Secretary BOWEN. I did, with the help of the fine staff that I have, make some appeals. I think we won a little, but I also learned a lot in the two or three days during which I had that opportunity.

SEQUESTRATION AMOUNTS RESTORED

Mr. NATCHER. Under the provision of the Gramm-Rudman law, I believe $790 million is sequestered from the Department of Health and Human Service activities. Can you tell us how much of this amount is restored in the 1987 budget?

Secretary BOWEN. I do not have that figure off the top of my head, but we will submit it to you.

Mr. NATCHER. Mr. Secretary, that is all right. And in the record, place a list of the 1986 sequestrations which are restored.

[The information follows:]

GRAMM-RUDMAN-HOLLINGS SEQUESTRATION

The sequestration in fiscal year 1986 for programs reviewed by this Subcommittee is $790.8 million in budget authority. Of this amount $290.9 million has been restored in the fiscal year 1987 request.

A list of activities in which the fiscal year 1987 request restores the Gramm-Rudman-Hollings sequestration follow:

Public Health Service: Health Resources and Services Administration; Maternal and child health block grant; and Hansen's disease services.

Centers for Disease Control: Immunization grants; Occupational safety and health research; Epidemic services; Program management; and User fees.

Alcohol, Drug Abuse, and Mental Health Administration Block grant.

Office of the Assistant Secretary for Health: Health services research; Health statistics; Adolescent family life; and Public Health Service management.

Health Care Financing Administration: Program Management; State certification; and Administration.

Social Security Administration: Low Income Home Energy Assistance Program; and Limitation on Administrative Expenses.

Child Support Enforcement.

Office of Human Development Services: Social Services Block Grant; Human Development Services; Runaway and homeless youth (ACYF); Family crisis and child abuse protective services (ACYF); Nutrition (AoA); Grants to Indian tribes (AoA); Federal Council on Aging (AoA); and Financial grants—Native Americans.

Family Social Services: Foster care; Adoption assistance; and Child welfare training.

SUPPLEMENTALS/REPROGRAMMINGS

Mr. NATCHER. Are there any of these 1986 Gramm-Rudman reductions which are serious enough to require a supplemental appropriation?

Secretary BOWEN. Not to my knowledge, but I shall make some further inquiries sir.

Mr. NATCHER. Do you plan to propose redistribution of any of the 1986 Gramm-Rudman cuts by reprogramming funds within appropriation accounts?

Secretary BOWEN. Not at this time.

Mr. NATCHER. Under rescissions, Mr. Secretary, in addition to the $790 million of automatic Gramm-Rudman cuts, your budget also proposes $725 million in rescissions. Last December the President, as you know, signed the 1986 Appropriation Bill because it met the target which he had agreed to in August. We took out $38 million at the time we had the conference report on the floor to meet this target.

If you will, explain why you are now proposing to rescind $725 million in addition to the automatic Gramm-Rudman cuts of $790 million? What is the reason for it, Mr. Secretary?

Secretary BOWEN. There have been many agreements between the Legislative and Executive branches in the last year, but it is a new ball game now with the Gramm-Rudman-Hollings reductions because it has established some new budgetary requirements which make us re-examine all of the funding priorities. It is sort of like a zero-based budgeting.

With only four percent of our budget that is discretionary and 96 percent entitlement programs, the 1987 budget with the rescissions requested, is the Administration's proposal which we think best fits

HHS's programmatic needs within the new constraints of the Gramm-Rudman-Hollings law.

EFFECT OF RESCISSIONS ON 1987

Mr. NATCHER. If any of these proposed rescissions are not approved by the Congress, what will be the effect on your 1987 budget request?

Secretary BOWEN. Well, it is possible that we might have to find other places to reduce to remain within our target level. We have put forth our best estimate of our priorities in the 1987 budget. But I do realize that you have the responsibility to act on the rescissions. Therefore, the Administration's proposed rescissions really are not breaking any previous promises, as much as they are new proposals to you that are intended to be consistent with the Gramm-Rudman-Hollings law.

Mr. NATCHER. We will insert in the record at the end of the hearing today your justifications for the 1986 rescissions.

NATIONAL INSTITUTES OF HEALTH

Mr. NATCHER. Mr. Secretary, as you probably know, Congress in general and this Subcommittee in particular, have always believed that one of our most important and successful government programs is the National Institutes of Health which supports biomedical research both directly in NIH laboratories and by grant and contract in universities and research institutions throughout the United States and, in fact, all over the world.

When I was elected as a member of the Committee on Appropriations, the National Institutes of Health had $77 million. Last year, you know, we appropriated $5,498 million. We believe that is the way it should be.

Congress—not the executive branch—has for the most part been responsible for the growth of the nation's biomedical research effort in the last 40 years. We do not feel that we were wrong about these additions. How do you feel not only as a former governor and the new Secretary, but as a doctor about the action that we have taken down through the years, as far as biomedical research is concerned, Mr. Secretary?

Go right ahead and tell me.

Secretary BOWEN. Well, first, let me congratulate you and Congressman Early, too, who I know has played a big part in all of this; and I congratulate Mr. Conte and all of the members of the Committee for your commitment to biomedical research.

The fact that this country does rank first in health research has been directly related to the past investments in science and technology; and maintenance of this position, of course, depends upon adequate funding for research and development.

And we do need the strong relationship between our educational institutions and industry and Government, in order to meet the goal of improving the health for all.

Our budget this year, for NIH, is $4.9 billion and that is about $124 million below 1986. As you know, it still will support 18,000 research project grants and 5,104 new and competing grants. It will support 523 research centers.

There will still be 12,860 continued grants. The average cost of each is about $156,700.

I would like to stress that we have about 50,000 scientists involved and that there are three Nobel Prize winners who are on the staff right now. I was surprised that there are 63 Nobel Prize winners that have research projects. So I think that the quality of the research will remain very high and will make up for the small reduction.

NUMBER OF RESEARCH GRANTS

Mr. NATCHER. Mr. Secretary, for some time, as you know, we have been receiving mixed signals from the Administration regarding biomedical research.

Last year a great deal of time and effort was needlessly expended in an attempt by the Administration to reduce the level for NIH research grants which had been approved by the Congress for 1985 by stretching appropriated funds out over a two year period. This was contrary to the Congressional intent.

The Comptroller General held that it was not lawful. We were forced to settle the matter by mandating the number of grants in the Supplemental Appropriation Act late in the fiscal year, after much uncertainty and confusion had been created throughout the research community.

The 1987 budget says that it will permit a continued, long-term, and sustainable Federal commitment to maintain NIH's unparalleled record of excellence in supporting biomedical research.

Nevertheless, Mr. Secretary, your budget proposes to rescind 1986 appropriations for NIH amounting to $62,867,000 in addition to 1986 Gramm-Rudman cuts totalling $230,192,000. Further cuts amounting to $124,015,000 are proposed for NIH in 1987. In total, the amount recommended for NIH in the 1987 budget is $417,074,000 below the amount appropriated for 1986.

In Fiscal Year 1985, NIH was able to support 6,246 competing research projects. Your budget proposes to cut this to 5,492 in 1986 and 5,104 in 1987.

On the other hand, the 1987 budget proposes increases for basic research supported by the Defense Department, the Energy Department, the National Science Foundation and NASA.

Now Mr. Secretary, my question is this, do you think that the numbers in the 1987 budget for NIH are consistent with the words which talk about a continued long-term and sustainable federal commitment to maintain NIH's unparalleled record of excellence in supporting biomedical research? Mr. Secretary, what would you say about it?

Secretary BOWEN. I think it is necessary that we also keep our eyes on 1991, and the necessity for a balanced budget by 1991. It would be impossible to keep the pace demanded previously with the amount of money that we can afford to spend.

Now I am all for research and as much as we can possibly spend on it, but I also feel that we need to keep in mind the quality. The research grants which are given must be studied very carefully and prioritized so that you get the most information for the money that is expended.

Every additional 100 research project grants creates a three year cost of $50 million and the increase from 5,000 to 6,500 projects added $750 million over the three years. And again, I would say, great if it is affordable and if we do not have to cut other projects that are also good to do this particular level of research, then okay—fund it.

Mr. NATCHER. Mr. Secretary, I want to thank you. And again, as I said in the beginning, we look forward to working with you, Mr. Secretary. We believe you are going to make a good Secretary. We say that to you frankly.

Secretary BOWEN. Thank you, sir.

Mr. NATCHER. Mr. Conte, I yield to you.

WELCOME FROM MR. CONTE

Mr. CONTE. Thank you, Mr. Chairman.

I want to join the Chairman in saying it's a distinct pleasure to welcome you here on your first appearance before our Subcommittee. You come, Doctor, with a very high reputation, and all of your actions up to now certainly bear that out. You certainly have a good man there to your right, Larry DeNardis, an old colleague.

There is just one thing I wanted to ask you. I understand that you are going to do some house calls via 60-second weekly radio messages, and I was just wondering whether you had a telephone number yet where I could call and get some free medical advice. [Laughter.]

I know there are a lot of things wrong with me. [Laughter.]

Seriously, though, I appreciate your invitation of breakfast, Mr. Chairman. We had a very lovely breakfast a few weeks ago. And I look forward to working with you and providing whatever assistance I can.

NUMBER OF PEOPLE LACKING MEDICAL INSURANCE

Mr. Secretary, what are your current estimates of the number of people in this country without medical insurance coverage?

Secretary BOWEN. I don't have the exact figure for those without any insurance at all, but it's a sizeable number.

Mr. CONTE. Do you think you can get that?

Secretary BOWEN. We can find it. It is between 30 and 40 million people, but I'm not sure—

Mr. CONTE. That's all right.

Secretary BOWEN. We will submit that for the record.

[The information follows:]

Number of Uninsured

We estimate that between 35 and 40 million people lack health care insurance at some time during the year. About half of these may be without insurance for a year or more.

PROGRAMS AVAILABLE TO THOSE WITHOUT INSURANCE

Mr. CONTE. What programs are available to provide medical care to those who do not have insurance and who cannot, on their own afford medical care? And how many people would you say are reached by these programs?

Secretary Bowen. Well, Medicaid, of course, is the biggest Government program to take care of the medical problems of the poor and those who do not have other resources. You have to be at the poverty level before you are eligible for medicaid. The big problem there, of course, is that so many or so much of the Medicaid funds have to be spent on long-term care and nursing homes, and I believe that 50 percent of the nursing home care for our people on Medicaid is from that source.

Mr. Conte. Given that the Community Health Centers are one of the chief ways we have attempted to fill in the gaps and provide care to those who might not otherwise get it. And given the large number of people currently without insurance, doesn't it make sense, then, not only to preserve and protect the community health centers, but even to expand them to reach areas currently without any such program?

Secretary Bowen. Certainly it makes sense to try to establish a system of medical care in which everyone has some opportunity to participate in it.

CATASTROPHIC INSURANCE

Mr. Conte. Mr. Secretary, I believe you know my enthusiasm for the idea of catastrophic health care coverage for older Americans. I shared with you that morning at breakfast an editorial in one of my local newspapers resulting from the plug I gave you on this, even prior to your confirmation.

Could you describe in brief an outline of your ideas in this particular area?

Secretary Bowen. Yes, I'd be glad to. Remember that we wrote the paper on this before I ever had any idea that I would be sitting in this position.

So our plan was to establish catastrophic health care for the acute illnesses and also for those who would be in need of nursing home care or for long-term illness. The first part of it, for the acute health care plan, would be cost neutral to the Government. It would be funded through an additional Medicare Part B premium. It would cover unlimited hospital days for the acute illness. There would be no co-insurance. There would be a maximum of two deductibles per year for Part A. It would limit the annual out-of-pocket expense to the beneficiary, and you could place that limit at whatever level you wanted, and the higher you placed it, the lower the premium, and the lower you placed it, the higher the premium. We used, for example, $350 as an out-of-pocket expense for the Part B.

It would eliminate the 12.5 percent in co-insurance for skilled nursing home facilities, and the rest of it would remain unchanged as far as home health care and hospice care would go.

We estimated—and it was costed out by actuaries, that for about $13—a little under in fact—per month, you could obtain all of this coverage. Now the fact that that sounds like a low figure is because the cost is spread over the 30 million people who would be the enrollees and potential beneficiaries, and also because only about

280,000 or so would actually have the catastrophic type of care per year.

But our senior citizens are really worried about two things, their finances and their health, and they wonder which one is going to run out first. And I think that the ease of mind that this would give them would be well worth the effort.

Now as far as part two, for the long-term nursing home care that would be required for someone with a stroke who had to be in a nursing home for a long period of time—or for Alzheimer's—there is no immediate solution to that without "catastrophic" cost to the Government or some entry.

We had the suggestion that an IMA, an Individual Medical Account, patterned after an IRA, could be created which would be tax-exempt to the individual, so that it would be ready, available, and used only for the long-term care for nursing homes. This has not been priced yet, but we are working on it, and these things that I have mentioned will be a part of the study that the President has requested us to do, plus——

Mr. CONTE. Will you include the nursing home also?

LONG-TERM CARE

Secretary BOWEN. Yes, long-term care for nursing home; plus the investigation of catastrophic care for all age groups. The study will consider, the newborn infant who weighs a pound and a half and has to be hospitalized for several months at great expense, or someone in an auto accident or a diving accident who breaks his or her neck and has a long-term type of need. We will be looking into all of these.

AFFORDABLE INSURANCE

Mr. CONTE. When I was talking to some of my senior citizens back home after I had breakfast with you, I found that there are some that really are almost at the poverty level, living strictly on Social Security and no other income, no pensions or anything.

Would it be possible to make some accommodation on premiums for the lower-income folks who might find even a small additional premium a very burdensome thing.

Secretary BOWEN. I think that would be a necessity, and that's one of the things that we would be looking into in the study. Wherever you draw the line, you're always going to have those who are just barely over—where it's going to be a difficult situation for them. But that does need attention, and that is one of the drawbacks of our present plan.

AIDS

Mr. CONTE. Doctor, on AIDS, I was very pleased to see the appointment of an AIDS Coordinator, and I believe the display of the AIDS budget as a single item under the Office of the Assistant Secretary for Health is very constructive and will contribute, I think, to the formulation of a plan for AIDS research and prevention activities, rather than having each agency fight for its piece of the action.

Are we at a point where we can put together a detailed plan of action to come up with the treatments and the vaccines, using the resource of each agency in a coordinated fashion, or are we still casting about for leads and hoping that if we put in enough money, someone will run across a new development?

Secretary BOWEN. No, I don't think, Congressman Conte, that there is fragmentation of the effort. I want to congratulate and thank you for your efforts in this, because, as I say, it is the No. 1 health problem in the nation. But the fact that the funds were all put in one pot, so to speak, I think will not have any ill effect. It will be a good effect, because it does emphasize the amount of money that's available and what is going to be done with it. The organizational efforts will remain the same and constant. And we have appointed Dr. Walter Dowdle as the coordinator for all of this, so that we have one spokesman and one boss, so to speak, to make sure that the funds are properly utilized.

Mr. CONTE. I have further questions, but my time is up.

Thank you, Mr. Secretary.

Mr. NATCHER. Mr. Smith?

WELCOME FROM MR. SMITH

Mr. SMITH. Mr. Secretary, like the others, I want to welcome you here, and I, like the others, have high hopes that your experience will help you handle this big job and help you in ways that others before you couldn't accomplish some of their objectives.

Secretary BOWEN. I still have a lot to learn, Congressman.

Mr. SMITH. Did I understand you to say that it would cost $13 a month for your proposed acute health care? Is that essentially the same protection that is sold for about $700 in private insurance?

MEDICAL INSURANCE

Secretary BOWEN. You are talking about Medigap insurance?

Mr. SMITH. Yes.

Secretary BOWEN. Well, the prices of Medigap vary considerably. I don't know what the lowest or the highest is, but I have heard of some policies that are $700.

Mr. SMITH. I think $700 is pretty close, but is that essentially the coverage we're talking about?

Secretary BOWEN. Yes, and it might even be more coverage, because of the unlimited hospital days. As I figure it, the $13 a month extra, would $156.

If you break it down between Part A and Part B, it would be only about $3.35 a month for the unlimited hospital days, but it would be about $9.50——

Mr. SMITH. The coverage would be substantially more than is in most of the Medigap insurance, then.

Secretary BOWEN. Well, it depends on the policy.

FUNDING FOR EDUCATION

Mr. SMITH. Everything is relative, you know. It doesn't take an Einstein to know that. But with regard to education, if we had enough money, we could have an emphasis on higher education, elementary education, secondary education, preschool education, and the whole works.

But relatively speaking, if there's not enough money, what areas do you think need to have priority?

Secretary BOWEN. You're talking specifically about education or medical education?

Mr. SMITH. Well, no. I'm talking about just general education, higher education versus secondary education versus elementary education versus preschool education.

Where do you think the federal support is most necessary?

Secretary BOWEN. Well, frankly, I feel that education should be left more to the States than to the Federal Government, and I don't mean that the Federal Government should not have any voice at all, but at the State level, of course, States put in billions of dollars in education, and at the local level, they put in more billions, and I think it would be best to leave the education, the vast majority of the education needs to the States.

I don't know what it is now, but when I was Governor, I think that the Federal Government had about 7 percent of the cost of education, and whether that's gone up or not, I really don't know.

Mr. SMITH. But suppose we're going to spend $12 or $14 or $15 billion or whatever it is on education. Don't you think or do you think there are some levels that need more support than others, relatively speaking?

Secretary BOWEN. I suspect that I would prefer—and this is just a personal opinion here—that it would go more in the area of higher education, perhaps again in the research areas. I think that is an area that—

Mr. SMITH. Well, I don't believe your budget reflects that, does it? You are proposing essentially to keep Title I in '87 like it was in '86 before the sequestering.

Secretary BOWEN. I don't believe that educational matters, other than the health professions education, are in our Department.

Mr. SMITH. That's true. When I said "your budget," I don't mean yours; I mean the Administration's budget.

Secretary BOWEN. Okay.

Mr. SMITH. And then vocational education has been cut by over 50 percent.

NURSING EDUCATION

Let's take a part that is in yours, then, nursing education. The 1983 Institute of Medicine report concluded that nurses with high-quality graduate education are a scarce resource. And the Administration, of course, has for many years contended that the supply of registered nurses in the country is very adequate.

In the budgeting process, as it works, as you are becoming acquainted with it, you find out that the Executive branch started to develop a budget for FY 1987 last October in the Departments. They go to OMB and back a couple of times, and every time something's cut out at that level. We have found on this committee that there was no nurse involved in that little group that decided what was to be cut. It's usually a doctor that was involved, and nurses get dropped out of the decision-making along the line. And this committee then puts them back in. We find that we have to restore nursing education in the budget.

GERIATRIC NURSING

But the part I am really concerned about is that I had a personal experience, and since then I've found out that a lot of other people have had similar experiences. Nurses in hospitals don't know how to take care of elderly people. Numerous people have told me that they have had a relative that was in the hospital, that died of pneumonia or fluid on the lungs that was acquired after they got to the hospital. They got a tranquilizer, laid on their back for 12 or 14, 15 hours, or one way or another, too often they just didn't know how to take care of elderly people.

There is a gap here, certainly, and this report indicates that, in the geriatric area. Apparently, we have enough of some kinds of nurses, but not enough of midwives and practitioners and researchers and those that are skilled in taking care of the elderly.

Do you agree with that or not?

Secretary BOWEN. I think that some of the things you mentioned on lack of care are more isolated instances than the routine.

Mr. SMITH. I thought they were, too. After I had this experience, eight members of Congress told me the same thing happened to one of their parents.

Secretary BOWEN. It has not been my experience or observation that there has been that kind of neglect. I would agree, perhaps, that nursing schools and medical schools should put a course on gerontology into their curricula. I think many of them already have. I certainly want to encourage that to occur.

I don't believe there is widespread lack of adequate care by nurses and by physicians, too. Actually, the total number of nurses has increased dramatically. I can give you the figures. In 1960, we had 500,000 nurses. In 1980, we had 1,273,000 nurses. By 1990, it is estimated that we will have just about 1.5 million, which means the number of nurses is adequate.

DISTRIBUTION OF NURSES

There may be some maldistribution of nurses, and there may be some specialties that are lacking.

Mr. SMITH. Not only that but in those numbers are a lot of nurses that are like school teachers, they are not in the nursing profession at the time. They are raising a family or they have retired or something else. We are really talking about the number that are available and the ones available that are skilled in the areas where they are most needed.

Are there enough nurses in the field of practitioners and an emphasis in researchers?

Secretary BOWEN. I can't answer whether there is enough or not. I don't know.

Mr. SMITH. This Committee is very interested and has been for years in trying to fill the gap on nursing education. You are qualified to do it. I wish you would take it on as part of your job to look at this nursing problem and determine or make some kind of a judgment as to what areas of nursing are not adequately filled at the present time.

Secretary BOWEN. I think the total number is adequate.

Mr. SMITH. Total numbers don't really tell us the story. Thank you very much.

Mr. NATCHER. Mr. O'Brien?

WELCOME FROM MR. O'BRIEN

Mr. O'BRIEN. Thank you, Mr. Chairman.

Mr. Secretary, welcome this morning. You carry with you an honored name from the Midwest.

Following in the wake of Mr. Smith's questions, and I will have more detailed questions later on, but I recently completed a stint out at Bethesda, NIH, as a result of having disc problems in my back. To touch on a little irony, years ago in real life, I was a trial attorney. I defended a lot of cases. I defended personal injury suits. I was always kind of a difficult cross examiner with respect to disc injury. Had I known then what I know now, I might have been a milder one.

What I wanted to mention to you about my experience out there just in a general way is that I was hospitalized for about a month on my back, getting the conventional disc treatment. I had more than one disc involved. It was quite difficult. While there, as both an in-patient and out-patient, I had an opportunity to move about and look at the various hospital like clinical situations at NIH and at Bethesda.

It seemed to me that the equipment was first rate. The highly professional personnel was also first rate. In every category I found that I really had nothing to be complaining about, with respect to the proficiency with which I was handled and it wasn't just because I was a congressman.

It was a pretty Spartan existence. There were no frills. A state villain in Illinois probably had better bedroom accommodations than I was living in. At the same time, I was getting the best of care and I thought candidly that our money was being well spent.

I just pass that on as a side line compliment. Not all conditions are bad out there. I am a typical example. I hope to make all my visits out-patient from here on. It was an educational experience.

Secretary BOWEN. Thank you. I will pass your compliment along to those who were responsible.

SHORTAGE OF NURSES

Mr. O'BRIEN. Following on the heels of Mr. Smith's examination, I, too, feel very strongly about the nurse situation. One thing that I think is weak out there is an area of shortage of that kind of personnel. It seemed to me that had I been hospitalized back in Joliet where my home is, at either Silver Cross or St. Joseph's Hospital, I would have been attended to by more individual people than I was at NIH. As I wandered around NIH looking at the situation, there were a large number of empty beds. I inquired why. The reason those beds are empty is not because there are not people who are in need of care, and in need of special attention, it is that they don't have the people adequate in numbers to take care of those empty beds. If they had more personnel, it seems to me they could take care of more critically ill patients.

I think that is all I really have right now, Mr. Secretary. I hope to address some other questions to Dr. Wyngaarden and other members who serve under you in a more specific way. In any event, we are glad to have you here.

Secretary BOWEN. Thank you.

Mr. NATCHER. Mr. Stokes.

Mr. STOKES. Thank you, Mr. Chairman.

Secretary Bowen, I join with my colleagues in welcoming you before our Subcommittee and look forward to working with you.

LACK OF HEALTH INSURANCE

I appreciated very much your comments regarding catastrophic insurance and the necessity for this type of insurance coverage. I am also concerned about the 25 to 35 million Americans today who have no health insurance at all, who also do not qualify for Medicaid. Nationally, public hospitals and clinics face incredible fiscal problems with the growing burden of providing medical care for those persons who fall in the category of being indigent.

Catastrophic coverage would help many middle class Americans but would not do very much for these persons who need good basic health insurance coverage.

Do you believe there should be a national commitment to provide some basic level of health care for everyone?

Secretary BOWEN. It would be my hope that everyone would have adequate access to care. I don't think I am ready to make a committment as to the level and so forth. That is an area which we are constantly studying and that will receive attention in my department.

PROVIDING MEDICAL CARE TO INDIGENT

Mr. STOKES. This whole problem that I am confronted with, and I am sure other Members of Congress have been confronted with, is that many public hospitals are now resorting to privatization and other options as a result of not being able to meet their own commitment to serving the indigent while at the same time serving that part of our populous that can pay.

Your budget calls for cutbacks of $1 billion in Medicaid, and nearly $5 billion in Medicare to be implemented primarily by reducing payments to hospitals and providers.

Can you tell us what impact you think these cuts would have on the ability of hospitals to provide charity care or care for the indigent?

Secretary BOWEN. You are talking about the so-called "disproportionate share" to hospitals? That is a subject that is under intense study. I believe that in the near future we will have some determination as to an adjustment to the DRG program and the Prospective Payment System concerning disproportionate share.

There are options that the State and local governments can do to help alleviate this problem. They could consider some possible rate mark-ups, for example, to commercial insurers. They could consider lump sum payments to hospitals with high volumes of the uncompensated care. They could consider a hospital revenue tax and subsequent re-distribution of the funds based on the uncompensated care. There could be some—I think some states have already done this—insurance pools to help the high risk individuals receive care. Also, I think some states have mandated continuation of insurance for those who are recently unemployed for a certain period of time.

These are just some suggestions that States could do in order to help alleviate that problem.

MINORITY HEALTH

Mr. STOKES. In 1984, your predecessor, Mrs. Heckler, announced that she was creating a task force within the Department to examine the persistent disparities in infant mortality and in overall health status between black and white Americans. After more than a year of exhaustive study, the task force report on black and minority health was released in October 1985.

This report documented significant health disparities between whites and minorities in the areas of infant mortality, cancer, cardiovascular disease, diabetes, chemical dependency and homicide, suicide and accidents.

As a result of the findings of this task force, Secretary Heckler announced the formation of a new Office of Minority Health with a $3 million budget within the Office of the Assistant Secretary of Health.

I have looked through your budget justification, the press release on your budget and your statement today before our Subcommittee. I see no mention of this Office of Minority Health. Can you tell us something about this Office under your jurisdiction and what we can anticipate?

Secretary BOWEN. Dr. Herbert Nickens was recently appointed to the directorship of the new office of minority Health. His Office will be responsible for monitoring the implementation of the many recommendations of this task force and coming up with some workable answers.

I compliment Secretary Heckler for having created this study. It did bring out information that will be very valuable to all people.

There is $3 million available to the office. We look forward to great things from Dr. Nickens. He is very knowledgeable about the entire area. He is very conscientious. I think he will create some education programs to help to correct this deficiency. Hopefully, in a matter of a few years, we can see the results. It is not going to produce any immediate reduction in the death rate of minorities. It is a blueprint for action.

Mr. STOKES. I would agree with you. I, too, think Secretary Heckler is certainly to be commended for having appointed a task force. The task force did a very comprehensive job. The research was some of the best we have ever seen.

Our concern will be about the recommendations and the follow-up on the recommendations of that report. I hope Dr. Nickens will have your instructions to follow through in that regard.

Secretary BOWEN. As a physician, I can assure you I am very interested in that. I'm not sure you realize it, but Dr. Nickens was my very first appointment.

Mr. STOKES. I am happy to know that.

BLACK/WHITE INFANT MORTILITY GAP

Let me also refer to a new Childrens Defense Fund report which document more alarming statistics on infant mortality. Among the findings of that report are that the black/white infant mortality gap in 1983 was at its widest in over forty years. Between 1982 and 1983, the post-neonatal mortality rate rose by three percent nationwide, the largest one year increase in 18 years. In 1983, for the first time in at least 33 years, older black infants died at a higher rate than the youngest white infants. CDF reported that babies born at low birth weight increased in 1983 among both white and black babies. The prematurity rate also increased for the third consecutive year.

I am sure you are aware of these findings. I would like to know if you can address this situation and what plans you might have for addressing this problem.

Secretary BOWEN. There are many programs that the Department has concerning newborn infants. This is one of my pet projects. When I first assumed this office—trying to get healthy newborns. It is a matter of emphasizing the factors that cause unhealthy newborns.

An educational program for the pregnant young people and for the physicians to stress that they obey the rules that the physician lays down to them, especially concerning adequate nutrition, concerning no smoking, concerning use of alcohol—these are three things that do cause low birth weight in babies. Of course the death rate in low birth weight babies is much higher. If you can prevent these situations, that is much better than treating them after they are born.

There are many things we are going to do, one of which I think is very important, and that is try to establish a linkage between the birth rate and the death rate so that we can try and put together a reason for the death of a particular infant.

There has not been any linkage between the birth weights and death rates. I think that is a very important step to try to determine the cause and then to see what we can do about it.

MINORITY PHYSICIANS

Mr. STOKES. Dr. Bowen, as a physician, I am sure you are aware of the fact that our nation has 25 to 30 million Black Americans, and yet fewer than 3 percent of the practicing physicians are Black physicians.

In the past, a stated goal of health professions programs has been to enhance the supply of minority health professionals. First, do you agree with this goal?

Secretary BOWEN. Yes, I would agree with the goal.

Mr. Stokes. Second, one of my concerns is that the report of the Graduate Medical Education National Advisory Committee concluded several years ago that "Care should be taken to ensure that programs designed to increase the number of minority health professionals are not thwarted."

Under your budget, you are proposing to terminate financial assistance to minority health professions students and subsidies to recruit and retain these students. How can we meet these goals or concern ourselves with enhancing the supply of minority health professionals in the absence of a budgetary commitment?

Secretary Bowen. There are three major assistance programs that we recommend be continued. These would be for the needy students. One program is called the Health Professions Student Loan Revolving Fund, which has $49 million, which is the same level as for 1986; then the Health Education Assistance Loans, the program called HEAL, there is money available in that for the needy students; and the nursing student loan program.

Mr. Stokes. Thank you, Mr. Chairman.

Mr. Natcher. Mr. Pursell.

Mr. Pursell. Thank you, Mr. Chairman.

I too want to welcome you, Dr. Bowen. As a midwesterner myself, I am very honored to have you serve as our new secretary.

VACANCES IN HIGH LEVEL POSITIONS

The problems of a new secretary have to do with budgets, personnel, morale, and all of that. Are you feeling comfortable now that vacancies at the highest level in HHS are going to be appropriately filled within sufficient time so that you have an adequate team around you to be an effective secretary?

Secretary Bowen. One of my first priorities was to get a team in place. We are making real progress at it, but you realize, I know, the length of time it takes to interview. If we have a candidate for a position from Florida, another from Oregon, another from Texas, by the time you get them all in and do the interviewing process, followed by the proper clearances, FBI checks and so forth, and then Senate confirmation for many of them—it takes time.

We are in the process—far along in the process of accomplishing this, and I would say in the next four to six weeks we should have most all of the vacancies in the top level areas filled so that we have permanent people—not in an acting status.

Mr. Pursell. So you intend to expeditiously fill those vacancies and build that team as quickly as possible.

Secretary Bowen. Yes, sir. We are working at it. I need them yesterday instead of a month from now.

STUDY OF CATASTROPHIC HEALTH

Mr. Pursell. Thank you. I too want to compliment you on your commission and study on catastrophic health. I think that is a national problem, and I look forward to your initiatives and your recommendations in the study. I would like to emphasize that I see it as a national problem, I think most of the members of the committee do likewise, and I wish you well in that effort.

I realize it concerns both the public and private sectors and I think there will be a combination, or some of both, in both parts of your study. I welcome your leadership there.

Secretary Bowen. I look forward to working with you.

NURSING PROGRAMS

Mr. Pursell. Some of us have worked hard over the years—Neal Smith mentioned it and George O'Brien, others, and the chairman—on the nursing programs, and it seems like we have so much medical testimony from doctors of this world, but, in my view, the Department lacks personnel appointments with respect to nursing. Dr. Carolyn Davis, who resigned as your HCFA director was a nurse, one of our appointments from the University of Michigan.

I would just be hopeful that you might look with favor on appointments of persons who have nursing health expertise and background, to provide balance and what I think is an important contribution to health policy. I think that is an important role for nurses—to have them at the highest levels of health policy-making.

Nurses now are looking at new studies which do show some shortages of baccalaureate advanced graduate work in the nursing programs. There are specific concerns that some of us have. I would be hopeful that, in the development of the Congressionally mandated new center for nursing, that it be comparable to the other NIH institutes. I believe that it is critical that your new staff look favorably on the grantsmanship from and development of that new center.

I think it is in a transition stage now. Pieces of the Federal budget and our health budget in the appropriation bill which deal with nursing have been line-item fragmented and it will be nice to see a new center, a comprehensive effort to further professionalize and set some real high standards for nursing in this country.

It is my hope, as this new center develops, despite the rescission proposal and debate about the $5 million to fund the center that this committee will be supportive in a concentrated manner, if you will, of trying this year to make that center a workable, effective, professional organization for the country.

The nurses in the country, I believe, Doctor, are looking to that, so they can get behind the effort to raise the professional standards of the nursing community, an already professional group of people who, admirably, are striving to make even better the quality of the good care they provide.

Secretary Bowen. The nursing center has been in a hold position. The hard choices of priorities on where to cut some of our programs to meet the Gramm-Rudman-Hollings mandate did cause us to put in our budget the rescission for the nursing center for the time being, but that means that we are simply asking Congress to take a second look at it, and in the event that the rescission is not okayed, then the NIH will be prepared immediately to proceed.

Mr. Pursell. I appreciate your comments and the indication that NIH will proceed immediately should the rescission not be approved. I do hope that you will be as supportive as you can.

CIVILIZED CODE OF CONDUCT

My last question, Mr. Chairman, deals with your earlier comment regarding a civilized code of conduct. You were commenting earlier about the need for government, schools, churches, families, media, and other influential structures of the country to reevaluate our problems in that area. I think it is a disturbing policy concern of all members of Congress as to how much you and how much we as a government can influence and change behavior to stabilize what we know are the great traditions of this early country.

I was wondering, Doctor, if you could further expand on that as far as what influence you think you can be to help change that concern of yours and many of us?

Secretary **Bowen**. I don't think Government alone can do it; it is going to mean a change of philosophy, so to speak, of communities, churches, teachers, every institution, and I believe that public debate will be stimulated by what the President has said about the family and what we are trying to say and what all of you will be trying to say. I know that it is a very deep concern to everyone. You can't legislate morals, you can't legislate some of these things to not happen; so it has to be done through changing of attitudes.

I think everybody in positions of authority should speak out. That is what is going to be necessary, and in every talk that I have given thus far in my short stay as Secretary, I have included such remarks. I hope that each time we do it, it has just a little effect on someone.

SPEAKING ENGAGEMENTS

Mr. **Pursell**. Do you plan on doing a great deal of public speaking as time permits and within the travel budget?

Secretary **Bowen**. As time permits. Preparing for these hearings, as I have mentioned to some of my colleagues, has been like studying for a final exam every night for the last three months. I am making talks; I will be making as many as possible. I will be including these thoughts in my remarks.

Mr. **Pursell**. I read your biography and I like your background and your credentials and qualifications. I think you will serve the country very well, and we wish you the best.

Thank you, Mr. Chairman.

Mr. **Natcher**. Mr. Early.

IMPRESSIVE STATEMENT

Mr. **Early**. Secretary Bowen, I want to commend you on your statement. Of the five secretaries I have served with, it is the most impressive statement I have heard, as far as what you said and how you said it. It is believable.

I am really impressed with your background, Mr. Secretary. Of the five secretaries I have served with, no one has been as qualified as you are to do this job. you are not only an M.D., you are in family medicine. You know, the doctor that goes into family medicine, at least in my perception, isn't going into become a rich man; he is going into it to deliver a service and to protect the profession.

So I am really impressed with both your statement and your background.

OMB RUNNING HHS

I want to make just a couple comments before I ask a few questions. What bothers me about HHS, in these last few years, Mr. Secretary, is that I have seen OMB take control of HHS. In my opinion, never before did a secretary get run over by the Director of OMB. Mr. Stockman, who is very knowledgeable, took control of HHS in my opinion, especially NIH.

I can see from your background that you are going to be loyal to everything, which is fine with me, but I think when you go back to the Califanos and the Schweikers, you find some people that stood up for what HHS represents. I think you are going to be that type of secretary.

Mr. Secretary, as Chairman Natcher said at the beginning, in my ten years on this committee it has never been partisan. It is not partisan at all. Your statement asks for cooperation, and you are going to get it. I really think that in the private meetings, you have got to restore what HHS stands for. It is going to be a very tough job because OMB is now running HHS. There is the potential for the United States to lead, and I just want to help you any way I can.

You know, Mr. Secretary, this committee tried to give autonomy to your department. These cuts are going to hurt. They are going to be very tough to enforce. But an even bigger threat than them is the fact that, under David Stockman and this administration, you are taking away the autonomy of NIH. Yoy are not letting the scientists have any control.

NIH GRANTS

We tried to do two things on this committee. We tried to establish a number of grants and protect it, but I think OMB tilted that against us and used it to take away autonomy.

The administration came in a few years back, under Mr. Stockman again, and tried to have multi-year funding. That was never the intent of Congress and it is not in the best interest of research.

You know, he lost the battle and won the war. He delayed spending that money and then the multi-year funding concept went out. Then in AIDS, we put the money in the bill under the Director's office, Dr. Wyngaarden, to give him autonomy. Now OMB is taking that money and they are using it as a vehicle to take away the autonomy. That's a real threat.

So I really wish you well. One thing you said was, what is affordable. I don't think the United States can afford to let Japan, West Germany and those other countries commit more money to research than we are. That is what is not affordable, in my opinion.

Mr. Secretary, with all your background and all your qualifications, you have only been here 90 days, so to speak, but there are so many accounts, and there are rescissions as well. As the Chairman noted at the outset, those rescissions were decided upon when you first came. But when we look at those rescissions, Mr. Secretary, how can you suggest to this committee or OMB suggest that we take a $51 million rescission in 1987?

A few years back, this committee committed a lot of money to swine flu, and the press criticized us afterwards when it didn't develop into the threat we anticipated. In my opinion, it was still wise that we found out it wasn't a threat. AIDS is a potential threat similar to the bubonic plague, according to the experts I am listening to, and you people send us a $51 million rescission.

AIDS

In your statement, and the President is always saying it is the greatest threat, you are going to cut $4.7 million for AIDS screening, testing and developing blood programs. You are going to take $3.1 million from expanding our vaccine efforts. You are going to take $700,000 from instructional studies on AIDS transmission.

This committee discussed AIDS and we said what we needed was discovery, because no one really knows anything about it, we had to develop a vaccine, and we had to educate everyone. And now you are requesting a $51 million rescission. Mr. Secretary, I will accept that you weren't there long enough to really be able to go in and lay the groundwork for that, but how do you justify it?

AIDS RESCISSION

Secretary BOWEN. First let me thank you for your kind remarks. I think your expectations may be great for me, but I will do my best. The Department certainly does feel that AIDS is the number one health problem in this country, and it is going to remain a priority until the problem is totally solved.

I think we have to really think about the rapidity with which one can or cannot effectively spend money on any particular project. The request does meet all the funding needs that were identified by the public health agencies at that time.

Rescissions reflect the amounts which were above the Administration's request. I am very really thrilled and very excited about all the progress that has been made. In fact, it is almost miraculous that in a disease that has only been known for about four to five years, so much already has been done. We know what causes it; we know how it is transmitted; and we have initiated many clinical studies of the promising drugs. There are drugs being investigated that would destroy the virus, and there are drugs being investigated that would stimulate the body's ability to improve its process of fighting off the other associated illnesses.

Mr. EARLY. Doctor, if I could just interrupt you there, though, because I disagree. I don't think we know what causes it. I don't think we know what is transmitting it.

I've talked to a lot of experts, and they believe that more than a million people might have it—that it is laying dormant and we can't detect it. We are not sure how quickly we can diagnose and identify AIDS, and that is a threat. They suggest that AIDS is totally a threat to young people. I mean, that's their suggestion, and they have suggested to me that we don't know what causes it, and we do not know how it's transmitted.

We have some restrictions. We know how we think it is not transmitted.

Secretary BOWEN. Well, I think the vast majority of scientific evidence does state that we know what causes it and how it's transmitted. But your statement about the potentials of the seriousness of the disease are certainly correct. There may be more people harboring the virus than we know about, but you wouldn't know that unless you routinely test everyone.

Again, I think that the progress that has been made is almost miraculous. I think you're going to find that there will be increasing numbers of AIDS until we do get the vaccine and the cure. But one factor that is encouraging is that the rate of increase has slowed, and this is an improvement.

Mr. EARLY. That's a positive thing, Doctor. You know, it was touted to us for a year that it was a homosexual disease. Now we're sure it isn't, because of what's happened over in Europe. I'm not looking to identify a problem and then throw a bucket of money at it; I want to be able to spend the money wisely. On the extramural side, we certainly could be spending a lot more, in my opinion, for discovery and for a vaccine. I don't think we are anywhere near the maximum on what we should be spending on that.

DIRECT COSTS/REIMBURSEMENT

I'm going to conclude my questions with one that's just a little different, Doctor. Because you're coming directly from a medical school environment, you must be able to sympathize with college and university administrators, faculty and scientists concerning the problems and conflicts surrounding the indirect cost reimbursement issue and the instrumentation issue.

What are your views on these two issues, and what direction do you believe we should be heading?

Secretary BOWEN. You are talking about the universities' overhead costs as far as the research goes?

Mr. EARLY. Yes, sir.

RESEARCH OVERHEAD COSTS

Secretary BOWEN. First, in keeping with the Congressional and the Administration concerns over the escalation of the costs of biomedical research, the Administration is proposing a fair-share, allocated overhead policy for indirect costs. Now of course, that varies from university to university, but the current rate for administrative allocated overhead is about 26 percent of the direct cost of the portion of the research grants. And it's pretty hard to identify just what all that 26 percent is for, and it's hard to say that all of that really is helping the research efforts.

And I certainly don't want to do anything to hurt the universities. I'm all for higher education, but I also am for getting as much of a dollar's worth of good out of every dollar spent on research. It seems reasonable that this component could be held to about 20 percent. And I think that that is a figure that has been discussed with the various universities involved——

Mr. Early. Mr. Secretary, I think you are totally right. I really do. I think we can bring that down. I just don't think we can eliminate it.

Mr. Secretary, I look forward to working with you, and I wish you the very best.

Secretary Bowen. Thank you.

Mr. Natcher. Mr. Porter?

Mr. Porter. Dr. Bowen, I, too, am delighted that you are at the helm of HHS, and I am particularly delighted with your professional background and your experience in state government.

When you get this far down the line in the questioning you begin to get to some of the esoteric questions, so I want to ask one or two of you.

TECHNOLOGY OUTSTRIPPING RESOURCES

One of your colleagues at the Governors' Conference—I would assume Governor Lamm of Colorado—has been telling not only the people of his state, but the people of the United States that we have great problems ahead in providing health care. He points out that our technology is outstripping our resources in providing health technology to people. We can make artificial hearts, but can we provide them to all who want them and need them?

What do you see ahead for health care in America in general? Do you see the need for rationing of health care technology? Do you see a crunch with costs outstripping resources? What's your prediction ten or twenty years down the line for America in terms of its ability to meet the health needs of the nation?

Secretary Bowen. We are facing just the very problems that you are discussing. Technology is progressing so fast that I suppose eventually everyone could be a possible candidate for an artificial heart, and certainly there isn't the ability, the facilities, or the funds to permit that to happen.

We certainly do not want any rationing of health care. Everyone is certainly entitled to receive or have access to as much as he can possibly get.

Our other big problem that fits into your discussion here is the fact that in the next 30 to 35 years, we're going to have about an 80-percent increase in the number of people above the age of 65. We're going to have a 220-percent increase in those between the ages of 75 and 84, and we're going to have a whopping 280 percent increase in those above the age of 85. It takes about one and a half times as much money to take care of someone above the age of 85 as it does someone at 65.

So with that tremendous graying of America, we are going to be facing a tremendous problem of taking care of our senior citizens. That's why I am intensely interested in developing a catastrophic type of care plan, because you can't wait and do it all in 25 years when you are going to be faced with a real catastrophe if we don't have it. I think we should be starting now.

Mr. Porter. Avoiding Governor Lamm's duty-to-die prescription for the elderly?

Secretary Bowen. Well, I hope he was misunderstood. I don't think he meant that as it sounded. Certainly, it is not anyone's duty to die. It is our duty to keep them comfortable and alive, and the older I get, the more I appreciate that. [Laughter.]

DEFENSIVE MEDICINE

Mr. **Porter**. One of the areas, Mr. Secretary, where we seem to be wasting a lot of money is in the practice of defensive medicine by our physicians and other health care providers. This once again, as it did in the mid-1970s, seems to have reached crisis proportions in America, and there is a good deal of activity going on in the states across our country to address this problem.

It became particularly evident here in Washington last year when we had a shortage of DPT vaccine for children because the pharmaceutical houses declined to continue supplying DPT vaccine because of the threat of lawsuits.

This, of course, is the problem product liability. Medical malpractice is another aspect of it.

What should the states be doing, and what should the Federal Government be doing, to address these kinds of problems that now appear to be of crisis proportions?

COST OF MALPRACTICE INSURANCE

Secretary **Bowen**. Well, you've hit upon one of the causes of the rapid increase in the cost of medical care. I could hardly believe that in New York City last year—I don't know what they're paying this year—but a neurosurgeon paid $101,000 for his malpractice insurance, just one year's premium.

I think being a neighbor to Indiana, you probably know that in 1975, we passed what I think is the model law for malpractice in the Nation. Medical liability, defensive medicine, and malpractice insurance all go together, and I think it should be studied. In 1975, I felt that it should be the State's solution, and I compliment you on your resolution. I have read it, and I think it is splendid I would hope that States would be able to solve this problem themselves.

But over the last eleven years, not much has been done. In fact, it has gotten much worse in many States. The Federal Government should do anything it can to encourage and stimulate the States to take action. We should begin to think about the role of the Federal Government in solving this problem, if states do not do anything. With the Federal Government paying for some 35 or 40 percent of all medical costs, it does run the costs for the Government considerably higher. I don't think that all of those costs are really necessary.

For example, if you fell and bumped your head a little bit and said, "Gee, it hurts a little here," or you felt a little dizzy, you're going to get a couple hundred dollars worth of X-rays. Even though the doctor knows full well that he's not going to find anything perhaps 999,000 times out a million, but he has to document the fact that he did do everything possible to determine any cause. I think it is a very important problem.

Mr. **Porter**. Since very few states have followed Indiana's lead in enacting reforms to make the risk of insurance companies predictable, what we need is more MDs as Governors of the various states and fewer lawyers. [Laughter.]

LIMITS ON SUITS

Secretary Bowen. Very fine. But let me say that our plan really was fairly simple. We put a limit on the time in which a suit could be brought. We put a limit on the amount for which a suit could be brought. We established a panel chosen by both sides to make a determination whether it was truly malpractice or whether it was a nuisance type suit. Oftentimes that settled it there. That essentially is the core of what we did.

Mr. Porter. Well, our resolution reflects those good ideas, and we hope the states follow your lead.

Mr. O'Brien. Would the gentleman yield to me?

Mr. Porter. Oh, absolutely. I yield to my colleague.

Mr. O'Brien. Governor, in dealing with those problems or that particular problem that Mr. Porter raises, did you give any consideration to assessing costs in the cases of litigation that maybe might be deemed—maybe not quite frivolous, but very close to that?

Secretary Bowen. Well, our plan wasn't very complete on the issue. It created two funds—one was the insurance fund in which the physician himself had $100,000 worth of insurance. They were charged a surcharge on that to create a patient's compensation fund from which the patients could be compensated for their damages.

I might mention that one other phase of our Bill stated that the attorney's charges were negotiable for the first $100,000, and then there was 15 percent limit on everything above $100,000. Of course, that was controversial, but it was adopted.

The report from the panel was admissible in court, and then the jury or the judge decided on the final amount.

Mr. O'Brien. With respect to the issue of meritorious litigation, however, it is always—I've always felt that some attention ought to be given to the assessment of the costs in the event—maybe it's because I was raised as a defense attorney—but the costs involved from frivolous litigation.

I think someone might make a pretty good case for saying that you shouldn't initiate it, and if you do, you will be hurt moneywise.

Secretary Bowen. Well, I would agree with that. But I think you will find that the claims attorneys would object very vehemently to that.

DELAY IN CHANGING DRG RATES

Mr. Porter. Mr. Secretary, let me ask two other questions. The budget reconciliation bill got a rule yesterday afternoon and is probably coming to the floor today. It contains a one-year delay in the transition to a national rate under our DRG system.

What is your prognosis for bringing that rate into full effect? Do you think, judging its effect on our Midwest hospitals particularly, that it is fair to continue the process of bringing forward a national rate in view of the inconsistency between the national DRG rate and the regulations for HMO variable rates?

Secretary Bowen. It's my understanding that Congress actually set the schedule for changes back in 1983 as to the timing of the changes. My present thinking would be that, unless there is a very good reason why it should be altered, that we should stay on the schedule.

VOLUNTARY PLANNING

Mr. **Porter**. Lastly, let me ask you about your general philosophy regarding voluntary family planning and Title X. Once again, the budget request proposes that these programs be funded through a block grant. I think Congress is not going to do that, so let's assume that it won't be done.

How does voluntary family planning fit into your own philosophy? What is its importance? What effect do you think it has on the high rate of teenage pregnancy in America? What role should parents be playing? Specifically, what notification should there be to parents when teenagers are provided with voluntary planning services?

It's an easy question. [Laughter.]

Secretary **Bowen**. With my emphasis on trying to reverse the problem of so many teenage pregnancies, certainly I feel family planning is very important.

As to the specific question about parents being notified when their child is using contraceptive devices, my personal feeling is that as a parent, I would want to be notified. As a practical individual, I have seen the trend in teenage pregnancies and realize there are so many sexually active young people, that if we are going to reverse this problem, we are going to need the cooperation of the parents and the family planning programs in order to get to the heart of the problem. I would support family planning.

Mr. **Porter**. Thank you very much, Mr. Secretary.

Mr. **Natcher**. Mr. Dwyer, you can run up until 12:00. If you do not finish, we will start with you when we come back. I yield to you.

Mr. **Dwyer**. Thank you, Mr. Chairman.

Doctor, let me join in the welcome that has been expressed by the Committee and wish you well and Godspeed in your new job. It is of paramount importance to the American people. I am sure you are very well aware of that.

VACCINE

I would like to visit the vaccine topic for a moment. Having spent some time in the state legislature before I came to Congress, I don't have much hope that all the state legislatures are going to act in concert and solve the liability problems that visit us with the vaccines.

Last year we had a shortage of vaccines in this country. The incidents of whooping cough and measles have nearly doubled in the last three years. Specifically, what plans does your Department have—I say "your Department" because you are there a very short while—to address this crisis in the country if it comes about?

Secretary **Bowen**. I think that a great deal is going to depend upon the availability of liability insurance for these companies. It is my understanding that there is only one company at the present time manufacturing the DPT vaccine. I believe their insurance runs out the 30th of June.

We are faced with a problem, and we need to help with a solution. We may have to look to Congress to help solve the problem of the liability for vaccines. Tort reform in this area is very important.

Mr. DWYER. From that statement, Doctor, is the Department prepared to send a legislative program over to Congress and urge and work for its passage? As I understand it, we have about a six month supply of vaccine. Our principal charge is to protect the health of the children of this nation, which is probably the overwhelming charge that we are all faced with. How are we going to respond to this?

Secretary BOWEN. There are two things that would solve the problem. One is if we could bar punitive damages. Another is to cap the pain and suffering awards that are made. That would make it more predictable for the companies on how they can handle this problem. The cost, incidentally, is just almost unbelievable. The vaccine for DPT, just a few years ago, was $0.11 a shot. Now it has increased 4,000 percent. That makes it a little more difficult to stockpile vaccines.

Mr. DWYER. From that, Doctor, I judge that we will be hearing from the Department with some type of a program.

Secretary BOWEN. A bill has already been transmitted to do those two things I mentioned.

REPORT FROM PRESIDENT'S COMMISSION ON ORGANIZED CRIME

Mr. DWYER. The President's Commission on Organized Crime issued their report a few days ago. Both the Attorney General and the head of the F.B.I. have responded to that report in part and pointed out the need to prevent the spread of drug abuse at the consumer level. They used the word "consumer."

They actually point to the program against cigarette smoking and its link with lung cancer as the type of a program that might be helpful to educate the consumer and destroy the consumer market for cocaine and heroin.

Have they contacted your Department with regard to actually coming out with a strong program to stress the linkages between the use of these drugs and their adverse effects on the health of the individual?

Secretary BOWEN. I have had no personal contact. It is possible that Dr. MacDonald or one of the others at NIH or CDC may have been contacted. I could find out for you.

Mr. DWYER. Would you please, and supply us with some information for the record?

[The information follows:]

PRESIDENT'S COMMISSION ON ORGANIZED CRIME

We have not had conversations with the President's Commission on Organized Crime on the specific relationship between drug use and health. The Commission did ask for our views on the importance of demand reduction activities, the role of research on the effects of drugs, and about drug abuse prevention and treatment and we did provide this information to the Commission.

PLANNING FOR SEQUESTRATION

Mr. DWYER. One final question. It is just a few minutes before 12:00 and we are going to recess. I have another meeting this afternoon. I will not get back to listen to the discussion on rescissions and sequestrations.

I am wondering if there is any plan afoot in your Department to face the sequestration problem come next October?

Secretary BOWEN. I will provide some information on that. I don't know.

Mr. DWYER. Is the Department discussing it? I understand you are brand new but you have staff that has been around for a while.

Secretary BOWEN. Yes.

Mr. O'SHAUGHNESSY. We are unable to do any planning for that contingency. The President's program is on the Hill. Sequestration would only be if that was not accepted. Than one would go back and sum up all the figures. We would look at what sequestration would be.

Mr. DWYER. Having been in business before I came to this job and having developed a certain amount of business prudence, I understand from all the print and broadcast media that the shortfall in the deficit reduction is anywhere between $20 and $35 billion, take your pick.

If that is the case, I would be surprised if you haven't started to talk about it at your level.

Mr. O'SHAUGHNESSY. I think a lot of that may depend on the defense numbers and the outlay rates. We are really unable to add anything.

Mr. DWYER. Wouldn't pure economic and business prudence dictate that you start to address that problem? I would be interested in knowing how you are going to suggest your priorities.

Mr. O'SHAUGHNESSY. Actually, sequestration would be an automatic process come August and September. We have set forth the Programs, Projects and Activities which would be the basic guideline on where the reductions would be taken.

Mr. DWYER. Could you supply that for the record?

Mr. O'SHAUGHNESSY. Certainly.

[The information follows:]

GRAMM-RUDMAN-HOLLINGS SEQUESTRATION FOR FISCAL YEAR 1987

The Gramm-Rudman-Hollings deficit reduction act triggers automatic spending reductions based on prescribed rules when the deficit is projected to be above the level set in the Act.

If the President's budget proposals for fiscal year 1987 are enacted as requested, there will be no need for the trigger mechanism.

If the enacted budget has a deficit greater than $144 billion the automatic trigger will be activated. The across-the-board reductions will be calculated based upon the percentage reductions required to bring the deficit to $144 billion in fiscal year 1987, except in accounts with special rules.

Since the law stipulates those programs that are exempt and those with special rules, there is no discretion in these reductions.

The only action that can be taken at this time is to convince the Congress to approve the President's budget as is.

Mr. DWYER. Thank you, Mr. Chairman.

Mr. NATCHER. The Committee will now recess until 1:00 p.m.

Afternoon Session

Mr. Natcher. The Committee will come to order.

Mr. Young, at this time, I yield to you.

WELCOME FROM MR. YOUNG

Mr. Young. Mr. Chairman, thank you very much.

Mr. Secretary, my colleagues welcomed you this morning and I would like to welcome you this afternoon. And while some of my colleagues from the midwest indicate their relationship to you because of their midwestern affiliations, all I can say is that most of the midwesterners that retire come to Florida, and my district, and we are very, very happy to have them. [Laughter.]

I have quite a number of questions that I would like to present to you and ask if you would answer them for the record. They are rather lengthy and I am sure the responses will also be lengthy, but in the time that we have available I would like to talk with you about something that I have been working on for a long time. And hopefully, you can give me some ideas or maybe your department could even take this matter on as an official subject to be reviewed.

NONADMITTANCE FOR EMERGENCY CARE DUE TO NO INSURANCE

A couple of years ago the daughter of a migrant worker in a Congressional district adjoining mine was locked in an abandoned refrigerator. That child was discovered and taken to one hospital, where she was refused treatment. She was taken to a second hospital, where she was refused treatment. And then she finally ended up at a third hospital, at Children's Hospital in St. Petersburg, where unfortunately she lost her life. The doctors there told me that had they been able to treat her sooner, it is very likely they could have saved her life.

That is a tragedy, and I do not think anyone disagrees with that, but very recently in my own district we had a case that I would like to relate to you and then discuss what we might do, if anything, about this.

CASE OF JASON ROBERTS

On May 11, 1985, Rhonda Drusco of Seminole, Florida took her six year old son, Jason Roberts, to the emergency room of the Metropolitan General Hospital in Pinellas Park. He had the symptoms of the flu. His attending physician, Dr. Kevin Chapin, diagnosed Jason's illness as Reyes Syndrome and it was subsequently proved to be an accurate diagnosis.

Dr. Chapin decided that the condition required emergency room care that his hospital did not have. They just do not have the pediatric emergency facilities there. Dr. Chapin called hospitals in the area to try to find pediatric emergency care space. The closest bed that was available was 20 miles away, at St. Joseph's Hospital in Tampa.

Dr. Chapin called the emergency room at St. Joseph's, explained the nature of the illness, and had confirmed to him that there was an available bed in the pediatric emergency ward. Dr. Chapin began to make arrangements for an ambulance to take Jason to Tampa, but he was interrupted by a call from St. Joseph's Hospital's admitting office, asking if Jason's mother had health insurance.

Dr. Chapin, being in a hurry—and the mother not being sure—responded he was not sure, but he did not think Jason had insurance. After quite a long pause, the caller hung up.

Dr. Chapin received a second call from St. Joseph's Hospital saying that Jason's mother either had to have health insurance or a prearranged financial plan before her son could be admitted to the emergency ward. Unable to meet either of these arrangements, Jason was refused admission to St. Joseph's Hospital.

This is happening at a time that a young boy has Reyes Syndrome and anybody with medical experience recognizes that Reyes Syndrome symptoms change quickly and the situation develops very rapidly.

The next closest pediatric emergency room bed was 130 miles away in Gainsville, at The Shands Medical Center. And they agreed to admit Jason, and they even arranged for an airplane to get him to Gainsville. But by the time he got there, at 1 a.m. in the morning, unfortunately the last emergency room bed there was filled because of accidents.

But Shands Hospital made arrangements for Jason to be transported an additional 70 miles to the Wolfson Children's Hospital in Jacksonville. The story goes on and on.

Jason survived. They put him into a coma intentionally to try to relieve the pressure on his brain. There was a question whether he would survive and even if he did, what his condition might be.

I spent considerable time, along with members of my staff, talking with the family, talking with Dr. Chapin who was the child's doctor, talking with the various hospitals who were involved and who were contacted but not involved. I even interviewed the reporter from the newspaper who did many stories on the subject.

CONCERN FOR UNINSURED

Incidentally, we also even pursued this through the requirements under Hill-Burton for emergency cases to be treated, but because the child was not actually in St. Joseph's at the time he was rejected, Hill-Burton did not apply.

After this very lengthy presentation of a case that I assure you—not only happens in Florida but also in other parts of the country. Is there anything that your department or this Committee can do to make sure that in the future the daughter of a migrant worker does not lose her life because she does not get medical care in time? Or what can we do to make sure that a child like Jason Roberts, with Reyes Syndrome—which is a severely life threatening disease—can be treated without having to risk his life because his mother may or may not have insurance?

The irony of this case is that after it was all over, it was determined that Jason's father—who lived in another state—did, in fact, have insurance on Jason and his medical expenses were covered by the hospital insurance.

I do not say this to be critical of anyone, but somehow we have got to find some way to guarantee that these kids are going to be treated when they need treatment, whether there is a question about their hospital insurance or not.

Secretary BOWEN. I certainly agree with you. I do not think that happens very often, but one time is too many. I know we read about that kind of situation in the paper and forget about the other million who were treated adequately. That one should not happen.

I think that the States should enter in and impose very severe penalties on hospitals that do not act ethically.

Second, if it were a Medicare patient, the Peer Review Organization would make sure that he or she is not turned away to another hospital without being in a stabilized condition and able to be transported. The Peer Review Organization is to investigate every such case that does occur.

I would think that the States should have a bigger part in what happens in emergency rooms.

Mr. YOUNG. We do have the requirement, under Hill-Burton, which is a federal requirement, that is hospitals that accept Hill-Burton funds have an obligation, at least for a certain period of time.

Would you be willing to assign somebody in your office to give some thought to this and possibly come up with some recommendations that Congress might consider? I tend to be somewhat of a states-righter, as I am sure you are having been a very distinguished governor. But sometimes the States might need a little nudging or sometimes they need some direction.

Secretary BOWEN. That we shall do.

Mr. YOUNG. If you would be willing to do that, this is one member of this Committee that would really appreciate it, because having had this situation happen right there in my district and—as a matter of fact—to a family that was almost my neighbor, not too many blocks away from where I live. It was a very heart rending situation and people all over our area were calling and writing letters and expressing their outrage. There were some suggestions of violence against the hospital, which I strongly objected to.

I recognize, as you say, that there are many, many, many more cases that are handled well. But it is a case like this that captures the public attention.

If you would be willing to work with me on this matter, I would certainly appreciate it and I would like to hear from whoever it is that you assign to this task. I would be happy to give them more details on this situation.

Secretary BOWEN. We shall proceed with a study on that.

Mr. YOUNG. As I said, the other questions that I have are fairly lengthy and I would just as soon submit them to you in writing.

Before I relinquish my time, I again want to compliment you on your credentials and the distinction that you bring to this position. I also would like to compliment President Reagan for having the foresight and the wisdom to choose such a person as yourself, with so well-established credentials to be a member of his cabinet.

Secretary BOWEN. Thank you, sir.

Mr. Young. Thank you, Mr. Chairman.
Mr. Natcher. Mr. Hoyer.

WELCOME FROM MR. HOYER

Mr. Hoyer. Thank you very much, Mr. Chairman.

Mr. Secretary, I share the sentiments that the other members of this Committee have expressed. I view your statement as a positive one.

Second, having served in the state legislature for 12 years myself, I think that gives you a perspective on what states can do and what they are doing. And of course, in your capacity as governor, you had responsibility of running a major executive department of our country.

All of that bodes well for your ability, it seems to me, to do the job.

I would add, however, that I was concerned about the fact that your predecessor left without making a judgment on the administrative side of the question concerning indirect costs, which I cannot make a judgment on.

But it seems to me, from the policy side of the question, that she had her heart in the right place, in terms of her focus and her realization of the importance of the issues with which your department deals.

But whether it was OMB or the White House, it is clear that there were some policy differences. I happen to believe—and I think this Committee believes, and I think its record shows, that we have sided with the Secretaries—if not expressed intentions, perhaps their subliminal intentions that may have been expressed in private.

Without going into that further, let me make some comments and ask questions of you.

SERVING THE NATION'S CHILDREN

The nation's children will be served as well or better than before by, "our proposals," you say, at page eight of your statement. Now Mr. Secretary, I know that you are familiar with the Children's Defense Fund. You may or may not agree with some of the premises, but I would be interested in your response to the observation of the Children's Defense Fund that more children have fallen into poverty in this decade than have been taken out of poverty.

CHILDREN IN POVERTY

In other words, there are more children living in poverty today than there were five years ago. Do you believe that is an accurate statement? And if it is an accurate statement, how does that relate to your statement that the nation's children will be served as well or better than before by "our proposals"?

Will we move towards reversing that trend if, in fact, it is a trend?

Secretary Bowen. I do not know the exact figures, but I am sure they are available. We could submit that figure to you, but I would simply like to reiterate that many of the programs affecting children have not been cut but they have actually been raised. Some have been reduced.

[The information follows:]

Children in Poverty

In 1981, the number of related children under 18 living in families who were in poverty was 12.1 million—19.5 percent of all such children. Corresponding figures for this year and for 1985 are not yet available from the Census Bureau. In 1984, the number of such children in poverty was 12.9 million—21.0 percent of the total—higher than in 1981, but down from the 13.4 million figure—21.8 percent of the total—1983.

Secretary Bowen. But I do not think that we are shortchanging the poor and the needy. To the contrary, in this time of budget restraints, are really protecting the benefits for the needy while seeking more efficiency and savings.

I firmly believe that there can be increased productivity in many of those programs, and I hope that we will be able to promote that type of productivity.

Our 1987 budget, for example, requests $26.7 billion for 15 key children's programs. And that is up almost $400 million over 1986 and it is up $1.9 billion over 1985.

Mr. Hoyer. Mr. Secretary, if I might stop you there. I saw that in your statement. In point of fact, however, that does not keep us even with inflation over those two years, does it sir? And I used four percent as a round figure, maybe 3.8%.

But if we did that in defense, Mr. Secretary, the President would say we were giving up.

Secretary Bowen. Well, at least—even taking inflation into account—we are not going backward.

Head Start

Mr. Hoyer. Let me talk about going backwards, if I can, Mr. Secretary. You mentioned Head Start in your statement, as well, and I did a little figuring on that. I was the one who added $12 million into Head Start. The Administration had proposed freezing it at 1984 or '85 levels, which was $1.075 billion.

I added $12 million in—and I say I added; I proposed and the Committee—and very frankly, the Chairman, added it in. The Committee was very accommodating. And because of his strong support and the Committee's strong support, we added $12 million and went up to $1,087 million. $46 million was sequestered, making the revised appropriation $1,040 million or a reduction of a $35 million. A backup in Head Start as a result of Gramm-Rudman.

You have now proposed going back to $1,075 million. Again, Mr Secretary, I would suggest to you that that is not keeping even. And if it was, in defense, the President would say we were making a vigorous retreat and were, in effect, raising a white flag.

Now pursuant to your answer, are we affecting greater productivity or efficiencies which will, as your statement seems to imply, allow us to serve as many children as effectively with, in fact, less dollars?

Secretary Bowen. The figures I have state that we will continue to serve 450,000 children, which is a record high. And that is close to 20 percent more than were served back in 1981.

Now, I do not know how many children should be served. I am sure there are some who are being missed. We are not reducing services because there are no increases over the 1985 level.

We were able to put $35 million more back, to bring it up to the 1985 figure.

Mr. HOYER. Mr. Secretary, what is your feeling, though? Head Start is a program that the President, in 1981, said was one of those programs that was working? Is it working?

Secretary BOWEN. Well, I do not think that anyone would deny that it is working. It is a popular program. We think it is popular, and we want to continue it.

The program was not protected under the Gramm-Rudman-Hollings Act, so we had no choice, as you know.

Mr. HOYER. I understand that under Gramm-Rudman you could not do anything to protect the program. Nor, frankly, could you probably do much about the budget that was presented.

My hope is that you will have a very substantial positive impact on the Fiscal '88 budget, which you will have under you aegis.

INFLUENCE ON INCREASED EFFICIENCY

Secretary BOWEN. I hope so, that I will have some influence on the increased efficiency and increased productivity of our programs. And I am convinced that that can be done.

Mr. HOYER. Mr. Secretary, I would ask you—and this is not a question, and I say this to most administration witnesses.

But if Cap Weinberger were standing there he would not buy your argument or make the statement that he cut the program or kept the program at the 1985 dollar level and suggest that he would make it more effective or more productive.

I am hoping, Mr. Secretary, that you as well, unless you really believe that we have more productivity and therefore can serve as many children as effectively, whether it is Head Start or some other programs under your aegis, that you will be a strong advocate in the Administration as those are on the defense side, for the objective of keeping America strong through maintaining our commitment to—in this case—children.

That is the long term best interest of the country, as you have so well pointed out in your statement.

Secretary BOWEN. I am committed to expressing my viewpoints on all of these and trying to use as much persuasion as I can to get my viewpoints across. That, I assure you, I will do.

DISPARITY BETWEEN MINORITY AND MAJORITY HEALTH

Mr. HOYER. Mr. Secretary, an additional subject, Mr. Stokes raised the question relating to minority health concerns, the disparity between the quality of health of the majority communities and the minority communities, particularly black communities. I was very pleased to hear of your appointment and would look forward to your findings when that report is issued.

Could you for the record, Mr. Secretary, state what efforts this Committee ought to be making to ameliorate the discrepancy in the quality of health being enjoyed by the minority communities in this country? That may be too broad and you may not want to do it for the record. If that is the case, we would like to have it in some other form.

[The information follows:]

Office of Minority Health

Both the Department and the Congress now have a "blueprint" for attacking the complex problems that disproportionately affect the health of minorities as a result of the report prepared by the Black and Minority Health Task Force. We now have the most comprehensive collection of information about minority health problems. Correcting these problems will not be easy, but knowledge and information about personal behavior, such as smoking, and its linkage to disease and illness can go a long way in closing the health gap. We ask the Congress to continue support of our research and education efforts.

Secretary Bowen. Let me make one preliminary statement and we can submit a greater amount for the record if you wish.

I think you have already done a tremendous amount by helping to authorize the study of the black and minority health task force. That is the first step. It has created the blueprint from which we can now act. Until we have some definitive recommendations on exactly what can be done—besides education of the people concerned and education of the medical community toward trying to make sure that we are correcting these deficiencies—I think we are just about a year premature to give full recommendations.

TEENAGE PREGNANCY

Mr. Hoyer. I have a lot of questions. I will submit most of them. You have talked about some of the problems that teenagers have, teenage pregnancy being one of them. Are you promulgating a specific program or recommendations to meet that question?

Secretary Bowen. We have several programs dealing with teenagers, all of which will help with this particular problem. Of course, the Maternal and Child Health block grant is one. Certainly there is plenty of room in the AFDC program to educate the young mothers—if not for the first time, to prevent a second and third time around.

Mr. Hoyer. That would be in terms of family planning?

Secretary Bowen. Yes. The States have the freedom in block grants for these types of education programs.

Mr. Hoyer. Thank you, Mr. Chairman.

BIOMEDICAL RESEARCH—INDIRECT COSTS

Mr. Natcher. Mr. Secretary, one of the perennial issues associated with Federal support of biomedical research is the extent of payment for indirect costs in connection with research grants. Very large sums are involved which are a vital interest to our nation's research universities.

On February 12th, the Office of Management and Budget published in the Federal Register, a proposal to modify present regulations by establishing a fixed allowance for university administrative costs.

At this point in the record, we will insert the relevant pages from the Federal Register concerning this matter.

[The information follows:]

leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under consideration. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attn: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C., by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at (800) 325-6000 (in Missouri (800) 342-6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to John A. Zwolinski, Director, BWR Project Directorate #1, Division of BWR Licensing: petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this Federal Register notice. A copy of the petition should also be sent to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and to Troy B. Conner, Jr., Esquire, Conner & Wetterhahn, Suite 1050, 1747 Pennsylvania Avenue, NW., Washington, D.C. 20006, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board, that the petition and/or request should be granted based upon a balancing of factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C., and at the State University College at Oswego, Penfield Library Documents, Oswego, New York 13126.

Dated at Bethesda, Maryland, this 10th day of February 1986.

For the Nuclear Regulatory Commission.

John A. Zwolinski,

Director, BWR Project Directorate #1, Division of BWR Licensing.

[FR Doc. 86-3217 Filed 2-11-86; 8:45 am]

BILLING CODE 7590-01-M

OFFICE OF MANAGEMENT AND BUDGET

Proposed Revision of Circular A-21, "Cost Principles for Educational Institutions"

AGENCY: Office of Management and Budget.

ACTION: Proposed revision to OMB Circular A-21, "Cost Principles for Educational Institutions".

SUMMARY: This notice offers interested parties an opportunity to comment on a proposed revision of Office of Management and Budget (OMB) Circular A-21, "Cost Principles for Educational Institutions." The revision is based on a recommendation by the Department of Health and Human Services and the Office of Science and Technology Policy to establish a fixed allowance for university administrative costs.

OMB Circular A-21 establishes Governmentwide accounting principles for the direct and indirect (allocated overhead) costs of Federal grants and contracts with colleges and universities. The Circular divides allocated overhead costs into seven "cost pools" that form the basis of a university's indirect cost rate. Four of these pools are administrative costs and, therefore, difficult to measure or evaluate in terms of their relevance to sponsored research projects. The remaining three cost pools are subject to less debate. They reflect costs of operation and maintenance, use charges for buildings and equipment, and libraries.

In Fiscal Year (FY) 1984 estimated Federal payments for university overhead were about $1.7 billion or 46% of an estimated $3.7 billion for direct scientific research.

The problem of rising overhead costs has been the subject of continuing and extensive debate by the Congress, the universities and research community, and others. This year the Inspector General for the Department of Health and Human Services (HHS) completed a study of indirect costs of federally sponsored research, confirming the existence of opportunities to control these costs. Sharing the concern about the rapid rise in indirect costs, the Office of Science and Technology Policy (OSTP) provided HHS recommendations for Governmentwide options to control indirect cost growth.

As a followup, HHS proposed a ceiling on university administrative overhead costs for federally-sponsored grants and contracts. The proposal is consistent with a recommendation made by the OSTP that a fixed allowance

based on average rates over a five-year period, be used to reimburse administrative overhead costs. The 26% rate shown in the proposal is the average rate for all major universities over the last five years. The proposal would subsequently reduce that fixed rate to 20%.

A fixed rate for administrative costs will go a long way towards solving the problem of rising indirect costs and at the same time reduce paperwork for the institutions. It will reform and simplify the indirect cost process and eliminate the need for complex reporting to support charges for allocated administrative costs.

This proposed revision will also help reduce the budget deficit, consistent with the President's FY 1987 Budget and the Gramm-Rudman-Hollings "Balanced Budget and Emergency Deficit Control Act of 1985," Pub. L. 99-177. It is estimated that this proposal will save $100 million in FY 1987 and over $200 million in FY 1988.

In order to achieve these savings, agencies will limit Federal reimbursement for allocated administrative overhead to 26% by April 1, 1986, and then further limit reimbursement to 20% by April 1, 1987.

It is, therefore, proposed that the following changes be made to Section F, Identification and Assignment of Indirect Costs:

- Change the heading of Section F.3 to "Administrative Costs."
- Revise Section F.3 as follows:

(a) The expenses under this heading are those that have been incurred for (1) General Administration and General Expenses, (2) Departmental Administration, (3) Sponsored Projects Administration, and (4) Student Administration and Services.

(b) Effective April 1, 1986, administrative costs allocated to sponsored agreements shall be limited to 26% of modified total direct costs (as defined in G.2) except that a lower rate shall be applicable where such rate is currently in effect for the total of General Administration and General Expenses, Departmental Administration, Sponsored Projects Administration, and Student Administration and Services.

(c) Effective April 1, 1987 the rate specified in paragraph (b) shall be reduced to 20%.

(d) Implementation dates up to one year later than those specified in paragraphs (b) and (c) are authorized.

(e) No documentation shall be required to support the rates specified in paragraph (b) and (c). An institution shall not change its accounting practices to reclassify administrative costs from indirect costs to direct costs of sponsored agreements.

(f) Agencies may authorize reimbursement of additional administrative costs only in exceptional cases where an institution can demonstrate undue hardship or detriment to project performance.

- Delete Sections F.4., F.5. and F.7.

Comments: Comments should be submitted within 30 days to: Room 5B 5000, Office of Management and Budget, 726 Jackson Place NW., Washington, DC 20503.

Dated: February 7, 1986.

Carole J. Dineen,

Associate Director for Management.

[FR Doc. 86-3114 Filed 2-11-86; 8:45 am]

BILLING CODE 3110-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Airport Traffic Control Tower at Dade-Collier Airport, Miami, FL; Closing

Notice is hereby given that on or about February 15, 1986, the Airport Traffic Control Tower at Dade-Collier Airport, Miami, Florida, will be closed. Services to the general aviation public of Miami, Florida, formerly provided by this office, will be provided by the Miami Air Route Traffic Control Center in Miami, Florida. This information will be reflected in the FAA Organization Statement the next time it is reissued.

Issued in Atlanta, Georgia, on February 4, 1986.

William H. Pollard,

Acting Director, Southern Region.

[FR Doc. 86-[illegible] Filed 2-11-86; 8:45 am]

BILLING CODE 4910-13-M

Airport Traffic Control Tower at Malcolm McKinnon Airport, St. Simons Island, GA; Closing

Notice is hereby given that on or about February 15, 1986, the Airport Traffic Control Tower at Malcolm McKinnon Airport at St. Simons Island, Georgia, will be closed. Services to the general aviation public of St. Simons Island, Georgia, formerly provided by this office, will be provided by the Brunswick Flight Service Station in St. Simons Island, Georgia, and the Jacksonville Air Route Traffic Control Center in Hilliard, Florida. This information will be reflected in the FAA Organization Statement the next time it is reissued.

Issued in Atlanta, Georgia, on February 4, 1986.

William H. Pollard,

Acting Director, Southern Region.

[FR Doc. 86-2907 Filed 2-11-86; 8:45 am]

BILLING CODE 4910-13-M

Maritime Administration

State Maritime School Contracts

AGENCY: Maritime Administration, DOT.

ACTION: Notice of Intent.

SUMMARY: The Maritime Administration announces its intent not to renew its contracts with state maritime schools.

FOR FURTHER INFORMATION CONTACT: Arthur W. Friedberg, Director, Office of Maritime Labor and Training, Maritime Administration, 400 Seventh Street, SW., Washington, DC 20590. Tel. (202) 426-5755.

SUPPLEMENTARY INFORMATION: The Maritime Administration does not intend to renew its existing agreements, as defined in 46 CFR 310.1(d) and 310.12-1, with the state maritime schools, including provisions pertaining to new student incentive payments, annual support payments and funds for maintenance and repair of training vessels.

These agreements will terminate on June 30, 1986. The affected schools are listed in 46 CFR 310.3 and are as follows:

California Maritime Academy, Vallejo, California

Maine Maritime Academy, Castine, Maine

Massachusetts Maritime Academy, Buzzards Bay, Massachusetts

State University of New York Maritime College, Ft. Schuyler, New York

Texas Maritime College, Texas A&M University, Galveston, Texas

Great Lakes Maritime Academy, Northwestern Michigan College, Traverse City, Michigan

This notice is in accordance with proposals contained in the President's FY 1987 budget message to Congress. If any new agreements are needed they will be developed in the near future. Any revisions to 46 CFR Part 310 also would be proposed for comment in a future rulemaking.

By Order of the Maritime Administration.

Dated: February 7, 1986.

Georgia P. Stamas,

Secretary, Maritime Administration.

[FR Doc. 86-3048 Filed 2-11-86; 8:45 am]

BILLING CODE 4910-81-M

RESEARCH DOLLARS

Mr. NATCHER. Briefly, Mr. Secretary, what do we have here?

Secretary BOWEN. I know both Congress and the Administration were greatly concerned about the costs of biomedical research rising and the desire to get as much research as possible out of every dollar appropriated, along with the overhead costs of the various universities continuing to go higher. The average of these overhead costs was about 26 percent. It is difficult to determine just what relevance some of this has to the research project itself. The figure of 20 percent has been established as a cap for these overhead costs. Theoretically, you should get six percent more in actual research rather than the overhead.

Mr. NATCHER. Mr. Secretary, to what extent did the Department participate in the development of the proposal? Did it participate?

Secretary BOWEN. I'm sure it did, but that came before my time.

Mr. O'SHAUGHNESSY. Yes, sir. The Department was very extensively engaged in this over a prolonged period of time. The Inspector General had for some time been maintaining that the rates—which basically were negotiated rates—were excessive.

Mr. NATCHER. What is the reaction from the universities? What have you heard since the publication in the Register?

Mr. O'SHAUGHNESSY. Negative, sir. It is a negative reaction.

Mr. NATCHER. Generally, down the line?

Mr. O'SHAUGHNESSY. Yes, sir.

Secretary BOWEN. I met three weeks ago with a couple of the University Presidents who complained about it. They said there were areas in which there could be compromises: if their paperwork and audit expenses could be reduced, there could be some tradeoffs made so that the costs could go down and both sides would still be satisfied. That dialogue, I am sure, will continue.

Mr. NATCHER. Are any actions, other than the matter you just mentioned, Mr. Secretary, planned with respect to indirect costs, that you know about at this time?

Mr. O'SHAUGHNESSY. I am not aware of any, sir.

HEALTH PROFESSIONS EDUCATION

Mr. NATCHER. Under health professions assistance, Mr. Secretary, we would like to have your views on the health professions education assistance programs administered by your Department.

As you know, there are a whole series of separate training programs in which such things as family medicine, health administration, public health, advanced nurse training, nurse practitioners and so on are a part. The President requested nothing for these programs in his 1986 budget. However, he signed the bill on October 22, 1985 which authorized the health professions program and he signed the 1986 appropriations bill which appropriated over $207 million for these programs on December 12, 1985.

You are now proposing to rescind the $147 million for these programs in the current fiscal year and to terminate all of them in fiscal 1987.

Mr. Secretary, what are your views in regard to this matter?

DIFFICULT RESOURCE CHOICES

Secretary BOWEN. This is another difficult choice. The education of physicians has been rather heavily funded for the past 20 years because of the severe shortage at that time. Funds were pumped into buildings to expand the medical schools and building new ones to the point that now we have essentially solved the numbers problem as far as physicians and nurses go. Admittedly, there are still some distribution problems. This is being handled by supply and demand. Where there is an area of need and there are too many in another area, they move to the area of need.

In 1970, for example, there were just 323,000 physicians and in 1980, 441,000. It is estimated that by 1990 there will be just short of 600,000. That essentially meets the numbers problem.

Still, in spite of the rescission request, we still plan to keep the three major student assistance programs for the needy students, who need assistance in financing their education. There are three such funds that are available—one for $49 million; another for $18 million; and another for $100 million. These programs will serve to help those who need financial assistance for their expensive medical education.

STAFFING LEVELS

Mr. NATCHER. In fiscal year 1982, the Department of Health and Human Services employed 142,248 full-time equivalent positions. Your 1987 budget proposes 122,873 full-time equivalents. This is 4,511 below 1986 and almost 20,000 below 1982.

Are you comfortable with the staffing levels proposed in the budget that are now before the Committee, Mr. Secretary?

Secretary BOWEN. A large portion of that difference is a related to the closing of the Public Health Service hospitals and the transfer of St. Elizebeths Hospital to the District of Columbia Government. Reductions in personnel create the need for innovative and creative activities; they can do the work. Again, I am a believer in the fact that you can always squeeze out an extra four or five percent by increasing productivity. I think the quality of the people who are working at the Department will be able meet that goal. I admit it will cause some strain.

Mr. NATCHER. How do you administer the employment ceiling within your Department? For instance, at the NIH Clinical Center, who decides as to the numbers? What is the procedure now?

CEILING DISTRIBUTION PROCESS

Secretary BOWEN. I can't give you the exact procedure. I will submit it to you, if you want, or maybe someone here can give it.

[The information follows:]

FTE CEILING DISTRIBUTION PROCESS

Initial staffing requirements are substantiated throughout the Department's budget formulation and execution process, which is supported by numerous agency on-going staff resource measurement, forecasting and control systems. DHHS agency ceiling allocation and reallocation is administered through the Departments "Modern Employment Retrieval Tracking Inventory" (MERTI) ADP System. Departmental Operating Divisions and their agency components such as the NIH Clin ical Center, administer personnel resources in accordance with levels provided through congressional appropriations action and standards which endure effective program operations. Total HHS staffing and FTE levels are controlled within the Assistant Secretary for Management and Budget's office, and each OPDIV head distributes and manages within their allocation.

Mr. O'SHAUGHNESSY. In that particular instance, sir, the Clinical Center is exempt, I believe, from the restrictions that are otherwise placed on the NIH.

Mr. NATCHER. Budget documents show full-time employment of the Department dropping from 132,501 in 1985 to 118,674 in 1988. That is a decline of over ten percent. The total budget for the Department including trust funds shows an increase from $332.1 billion to $415.1 billion during this same interval based on your budget projections.

Mr. Secretary, explain if you will, please, how it is possible to administer an increased budget with ten percent fewer people? Do you feel it can be done?

Secretary BOWEN. If we find that it is not being done, we will come back and ask for enough staff to make it work. The "answer," is yes, I think it can be, but we will monitor it very carefully. If we feel that the job is not being done, we will complain about it.

Mr. NATCHER. If you will insert into the record at this point a table showing the full-time equivalent employment level for the Department broken down by agency and account from fiscal 1981 through 1987 with appropriate comparisons, if you will, please.

[The information follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
STAFFING - FTE, 1981-1987

April 9,1986

	FY 1981 Actual FTE Usage	FY 1982 Actual FTE Usage	FY 1983 Actual FTE Usage	FY 1984 Actual FTE Usage	FY 1985 Actual FTE Usage	FY 1986 FTE Ceiling 2/	FY 1987 FTE Ceiling
[illegible]	9,011	2,596					
[illegible]	—	—	2,536	4,008	3,574	3,294	2,489
[illegible]	[illegible]	3,956	4,606	4,198	4,341	4,015	4,015
[illegible]	[illegible]	12,645	13,415	13,662	13,108	12,689	12,689
[illegible]	[illegible]	1,624	1,660	1,643	1,556	1,501	1,501
[illegible]	[illegible]	2,566	5,803	1,757	—	—	—
[illegible]	[illegible]	247	—				
[illegible]	[illegible]	1,675	1,000	1,167	1,430	1,170	1,184
Subtotal, PHS	[illegible]	29,077	29,264	28,615	21,669	22,838	22,038
[illegible]	[illegible]	4,031	4,125	4,090	4,020	3,900	3,757
[illegible]	[illegible]	83,871	87,261	80,916	79,055	77,478	74,461
[illegible]	[illegible]	[illegible]	(1,511)	(88)	(88)	(84)	(77)
[illegible]	[illegible]	(83,870)	(81,977)	(79,925)	(77,741)	(76,167)	(73,270)
[illegible]	340	328	341	344	331	307	297
[illegible]	[illegible]	1,023	1,111	1,200	1,158	1,125	1,105
[illegible]	—	179	144	59	58	57	36
[illegible]	[illegible]	484	611	677	383	401	371
[illegible]	[illegible]	1,384	1,348	1,160	1,307	1,273	1,214
[illegible]	[illegible]	2,167	2,517	2,661	2,462	2,241	2,211
[illegible]	[illegible]	138	111	109	36	41	38
[illegible]	[illegible]	4,236	5,588	4,734	4,147	3,948	3,832
[illegible]	[illegible]	129,813	124,079	118,286	112,467	109,603	105,526
[illegible]	[illegible]	7,118	7,293	7,257	7,190	6,947	6,942
[illegible]	[illegible]	10,283	10,309	11,039	11,554	10,817	10,400
[illegible]	53	36	36	31	32	22	5
[illegible]	18,868	17,435	17,638	18,327	18,776	17,781	17,347
TOTAL, HHS........	[illegible]	147,248	141,715	136,609	131,243	127,384	122,873

1/ HRSA was established in FY 1983 by a merger of program activities from HS and HRA.

2/ FY 1986 ceiling amounts have been made comparable to the FY 1987 budget level by adjustments for transfers; transfers were between SSA and OS/OIG, HCFA and SSA and OS/OGM and OHDS; actual usage amounts for FY 1981/1985 are comparable.

WELFARE REFORM

Mr. NATCHER. Mr. Secretary, in the President's State of the Union Message, the President, as you know, charged the White House Domestic Council to present him by December 1, 1986 with an evaluation of programs and a strategy for immediate action to meet the financial and safety concerns of poor families.

What can you tell us about the plans for this study? What has taken place up to this time?

Secretary BOWEN. Since it will be under the leadership of Mr. Meese, I do not know what the full plans are. I do understand he has appointed Mr. Bauer, who is the Under Secretary in the Department of Education, to head up the study. I do not know the details of how he intends to approach this study.

In the study on catastroplic health care, we are going to have three task working groups to study each one of the three phases of the catastrophic coverage. We are going to have an executive committee headed by my Chief of Staff, Mr. Burke, to whom these three working groups will report. In addition to that, we plan to have an advisory committee—a public and private sector advisory committee to the Secretary. They will prepare a report to the executive committee. Those reports will be completed around the first of October, at which time the panel will be dissolved, and we will begin to write the final.

I have heard a rumor that the welfare reform study will be conducted in the same manner, but I do not have any other details.

WORK INCENTIVES PROGRAM

Mr. NATCHER. As you know, we have an existing program, the Work Incentive or the WIN program, which has been in existence now for many years, which aims to train welfare recipients and to provide child care for them, so that they can earn a living.

Why does your budget propose to terminate this program?

Secretary BOWEN. The WIN program has not been as effective as we hoped. We do not plan to forget about this area of need; we want to replace it with what we call our Work Opportunities Initiatives program, which would, we think, be a great deal more effective because it would do more to assure that the individuals who are to engage in true work activities.

The WIN program simply asked them to register. Of the 592,000 who registered in the regular WIN program in 34 states in 1984, only 32,000 of them or 6 percent, were actually in the work and training component of the program (Public Service Employment, on-the-job training or 13 weeks of work experience). And that means there were too few of the WIN registrants who gained any economic independence. In fact, the percent that left welfare was no greater than would have been expected to have left without that program.

The Work Opportunities Initiative program will, I think, be a great improvement because it doesn't just ask people to register. It is mandatory that the able bodied recipients and those who are employable register and are placed in a Job Search program or a work training program. They can be in a grant program in which money is given to an industry to pay a portion of the salary, so that the recipients can get on-the-job experience.

And this Work Opportunities initiative proposal that we have put forth would be open-ended—not just a capped program. There would be a 50/50 match for the administrative costs, we have asked for $200 million to be set aside for that to match with the States. Actually, that would be more than is available for the WIN program.

We think it's a replacement with something that actually is better.

Mr. NATCHER. Mr. Conte, I yield to you.

MOST PRESSING PUBLIC HEALTH ISSUE

Mr. CONTE. Mr. Secretary, what do you consider to be the most pressing public health issue facing the Department and the country?

Secretary BOWEN. Well, I think AIDS has to be considered the biggest problem as far as disease goes. The inavailability of insurance for catastrophic illnesses has to rank at the top also.

Mr. CONTE. Speaking of AIDS, I understand, Mr. Secretary, that you have sent over to OMB a draft regulation to screen all aliens who apply for permanent residency to take the HTLV-3 antibody test. It is my impression that the test is not always accurate, and it is not a test for AIDS itself and was not, I believe even by your own Department, meant to be used a screening test for AIDS.

Why do you think this is a good idea, Mr. Secretary?

Secretary BOWEN. AIDS is the No. 1 public health problem. We do not permit people to come into the country with a diagnosis of Syphilis, or Tuberculosis, or Leprosy, and it seems to me that AIDS is a greater menace than any of those illnesses.

I realize that as a screening test, it may not be adequate if it's positive they would need to have the Western Blot test to make sure. The problem may be that some of the laboratories in some of the other countries may not be adequate to do this yet. But this is just in the preliminary stage, and it's open to discussion. It just seems right to me that if you don't let people with Syphillis, Tuberculosis, and Leprosy in there we certainly should include AIDS in that category.

ALZHEIMER'S DISEASE

Mr. CONTE. As you may know, last year funds were provided for a demonstration health care project for AIDS patients and Alzheimer's patients.

It would seem to me that Alzheimer's patients have many of the same devastating problems and need some of the same assistance in devising better and less costly methods of care. Our concerns regarding Alzheimer's have been assisted by the Special Task Force brought together by your predecessor with some of the best researchers and administrators serving on it.

Is it your plan to keep that task force in action during your tenure in the Department?

Secretary BOWEN. Well, I think Alzheimer's is probably one of the biggest public health problems as far as our elderly go. The answer would be, "yes," that needs to be continued. They are making good progress now—still far from a cure, but they are finding a lot more information as to the cause and may be finding that it is not really, totally a disease of aging. It might have some other metabolic causes.

Mr. CONTE. I'm pleased to hear that. In our appropriation report last year, I sponsored language requesting the task force to issue a followup of its first report, paying particular attention to the devastation that families face from long-term costs, financial and emotional both, in caring for an Alzheimer's victim. Even after a family has spent all of its resources, many types of services are not covered by Medicaid.

How big a problem do you think this is for families, and do you believe that there is a larger federal role to be played in helping to provide the kinds of services that Alzheimer's patients need?

Secretary BOWEN. Again, I would have to come back to the need for long-term catastrophic care. Right now, that's about all that can be done—to make sure that they get good medical care and then good physical care until the researchers have come up with some methods of prevention.

We are working on the report, and I am told that it will be available within a few weeks.

NATIONAL INSTITUTES OF HEALTH

Mr. CONTE. I know you have answered some of my questions. I am going to ask you one here with respect to the National Institutes of Health, which has always enjoyed great support from the Chairman and the Subcommittee.

The budget proposes a total of 18,000 grants for FY '87, which would mean 5,140 new and competing grants compared with 6,200 in FY '85, 6,100 in FY '86.

Why is 18,000 total grants an appropriate goal for research at the National Institutes?

Secretary BOWEN. The 18,000 is a "sustainable" effort over the next many years. To reach that level, we had to reduce some of the new and competing grants because of the expense that would be incurred in the out-years.

As I mentioned for every 100 projects, there is a $50 million projection of increased expenditures over the next three years. In order to keep a sustainable level, the 18,000 number was reached, and 5,100 new and competing grants would be necessary.

Mr. CONTE. Yesterday, I noticed a supplemental budget request was sent up by OMB requesting that the bill language be changed from "require 6,100 new grants "to" such a number as the Secretary of Health and Human Services might determine."

Now I wouldn't have too much trouble with that if it really were up to you, Mr. Secretary, to decide on the appropriate number of grants, because I know you would make the right decision. But I don't know if you followed it when we got into a little hassle last year with OMB, which tried a backhanded maneuver to reduce the number of new grants from 6,200 to 5,000 by providing a three-year advance funding to some of the grantees. And that was how we ended up with that number of grants in the bill.

What assurance would we have if this budget supplemental were passed, that OMB would not resort to its old tricks and dictate some arbitrary low number of new grants?

Secretary BOWEN. Right now all I could say is you'd have to take my word that I would argue on behalf of the most grants that we could obtain within the funds that were allotted. I want research to continue; I know you do, too; and we'll work together on that problem.

INDIRECT COSTS

Mr. CONTE. In regard to the indirect costs a notice was published in the Federal Register on February 12th changing the OMB circular on indirect costs by limiting them to 26 percent on April 1st and 20 percent a year from then.

The question that I have is, is this policy again being proposed to be applicable solely to HHS, or is it across the board, all functions?

Secretary BOWEN. I asked that same question, and it was my impression is that it is across the board.

Mr. O'SHAUGHNESSY. It is.

Secretary BOWEN. I didn't want to be the only one——

Mr. CONTE. Well, that was always the argument the Chairman and I always had, why pick on HHS? If this is a good policy then it should fly across the board.

Shouldn't there be a little more time to debate this proposal?

Secretary BOWEN. I always welcome debate.

Mr. CONTE. Are the Inspector General's report on indirect costs and the recommendations of the Office of Science and Technology Policy on which OMB appears to base its proposed revisions even available to the public? I haven't been able to get any copies of then?

Mr. O'SHAUGHNESSY. They should be, sir. Certainly the Inspector General's reports, I know.

GRAMM-RUDMAN-HOLLINGS CUTS IN SSA

Mr. CONTE. In FY '86, Doctor, the Social Security Administration proposed reducing employment, supported by the limitations on the administrative expense account, by 1,600 FTEs.

Now we were very wary of large-scale cuts resulting in poorer service to the Social Security recipients and therefore added $30 million to that account to restore up to 1,000 of those positions. However, it is my understanding that Gramm-Rudman-Hollings wipes out that $30 million, in fact reduces the amount available for administrative expenses by $144 million; is that correct?

Secretary BOWEN. I don't know the exact figures.

Mr. O'SHAUGHNESSY. Yes, it is, sir.

Mr. CONTE. That is correct?

Mr. O'SHAUGHNESSY. Yes, it is.

Mr. CONTE. It makes you wonder how many who voted for Gramm-Rudman-Hollings realized the impact it was going to have on Social Security when they're going right along saying that it exempts Social Security.

Well, thank you, Mr. Chairman. I guess my ten minutes are up?

Mr. NATCHER. Mr. Early, I yield to you.

Mr. EARLY. Thank you, Mr. Chairman.

Doctor, on any of my questions if you want to delay in answering, that's fine. I'm really not trying to put you on record. I'm just discussing in general several things.

FILLING VACANCIES

Doctor, the last couple of years, the Department has had an awful record, in my opinion, for getting appointments filled or filling vacancies in the particular Institutes. Do you have any plan to speed that up?

Secretary BOWEN. I'm not certain I understand your question.

Mr. EARLY. Well, what happened was the Secretary had a fight going on with the White House, and the appointments weren't going in, and vacancies weren't getting filled.

Secretary BOWEN. You're talking about a lot of the top positions. We are not really having that problem now. In fact, I would have to say we are getting good cooperation.

The problem is in the process of interviewing many people for top jobs. Calling them in from various areas of the Country, so, we can interview them. You do that for six or eight applicants, and then you decide on one. Then it goes for clearance, and then most all of these have to have FBI checks. That takes two to six weeks, and following that, many of them have to have Senate confirmation. We're in the latter stages of this process with many of our people now.

Mr. EARLY. That's fine. But you know, by not filling them, the country pays a price. I'm not a big booster of screening committees and this one studying it and that one studying it. You know, I'm much more comfortable when the boss makes a decision and sends in a name.

If the American public likes President Reagan for anything, it's because he's a decision-maker. I really hope we don't have that big list of screening committees and everything else.

Secretary BOWEN. I didn't mean that we have screening committees. We're making our own decision on that.

Mr. EARLY. Okay. Let me ask you about a parochial thing, and I would really like you to look into it.

MASSACHUSETTS REIMBURSEMENTS FROM HCFA

The state of Massachusetts has really been hurt by HCFA asking the hospitals for repayment. Doctor, the hospitals haven't done it because they can't afford it. We really think it's a poor interpretation of what the rules were concerning the waiver. The hospitals are hurting in that the delivery of service is uptight because of this repayment, if it ever happens.

All I would ask is, for Mr. Conte and myself that you look into this matter personally. Believe me, it's really not fair, if they ask the hospitals to repay that money, you know, and it's been going on for awhile.

Mr. BURKE. We have had meetings with the Counsel for the Massachusetts Hospital Association. A mechanism has been put in place. I spoke on the phone just yesterday with the attorney.

Things seem to be coming along. The question of equity remains to be determined, in all fairness, Congressman.

The State did agree to a set of rules under which they would be reimbursed x amount. The reimbursements, in fact, were in excess of that, and HCFA is now seeking recoupments along a schedule.

The Hospital Association has some question on the magnitude of the recoupments, not on whether or not recoupments are required. We are in the process of furnishing their attorneys, Hogan & Hartson, with all of the data that they have requested. Yesterday I directed the Health Care Financing Administrator to put a single person in charge, with responsibility for coordinating all of the requests for data, so they can be put on a fast track and processed on an expedited basis. They were complaining that they had to go one place for this piece of information and another place for that, and they felt as if they were getting the runaround. That has been corrected.

We have a schedule we are going to meet. If HCFA and the Massachusetts Hospital Association cannot come to an agreement on what is a fair and equitable settlement, there is a procedure that will bring it to the Secretary office, and I will personally intervene on it.

Mr. EARLY. I can't ask for any more than that. I know the hospitals and HCFA don't interpret the waiver in the same way, but if you do put us on the fast track, and if the Secretary can take a peek at it, that will be just fine.

Our hospitals, both private and public, are hurting so bad they can't afford the repayment. Really the one that is getting hurt is the service. I am sure as an ex-governor, you can appreciate that.

COST OF MEDICAL SCHOOL

Doctor, with regard to manpower, you spoke of the funds for hospitals. Sure, we might have a surplus of doctors, but we have changed from the thirties. You go to med school now by your ability and not by your pocketbook and I hope we continue on that track. If we just say we have a surplus of doctors, med schools are going to be able to fill up with these kids and we won't achieve what we wanted.

The three funds that you spoke about being available, two of them, the nursing revolving loan fund, for which $18 million is available, and the health professions revolving loan fund, which has $49 million, are going to be reimbursed at a rate that just keeps them neutral. We are not doing anything to provide new capital for these accounts.

We have used good foresight in refueling those two particular funds, and I think the long-range goals won't be achieved if we don't increase the capital in both these funds. If you would just look at that, I would appreciate it.

On the HEAL program, I will be a little more specific. You know, you say you have $100 million. You do have a request in for $100 million, but your justifications show that the amount available after sequestration is $389 million for 1986. Now, that is a $289 million reduction, and in your justification, you show that the number of borrowers using HEAL is going to go from 39,292 down to 10,000. I think the amount you have in your justification isn't going to be adequate. If you would look at that, I would appreciate it.

Mr. Secretary, as a father that has a daughter becoming an R.N., it cost me $12,000 a year, and I have got four in college. I don't know how anyone can go in to such an honorable profession, make that type of investment, $50,000 over four years, and think she can ever get it back. If we cut back too much on the manpower programs, I don't know how the mechanic or the shopworker or the fireman or policeman is going to be able to let his kid go into nursing. I really think you have to look at that, Mr. Secretary.

Secretary BOWEN. All right.

Mr. EARLY. Mr. Secretary, you were associated with Indiana Medical School?

Secretary BOWEN. Yes.

Mr. EARLY. What is the tuition out there? Is that a public institution?

Secretary BOWEN. Yes, it is a state institution. I believe that it is around $3000.

Mr. EARLY. The public med schools we can live with, but we have got four in Massachusetts: Harvard, Tufts, B.U. and University of Mass. The University of Mass. has a fair tuition. The other three are in excess of $20,000.

Secretary BOWEN. I see that.

Mr. EARLY. That is going to be really tough. If you would look at that, I would appreciate it.

VACCINE SUPPLY

Mr. Secretary, could you give us a little direction? Mr. Dwyer had asked you about the vaccines, and your answer to him about the short supply was that legislation was introduced. I don't know what the legislation is, and I don't know if it will pass, but often legislation associated with keeping a budget request down really doesn't happen. Have we got a fallback position on that if the legislation doesn't pass? How are we going to keep our vaccine supply?

Secretary BOWEN. That is something that we have to get working on rapidly and something we do need everybody's support on to solve the liability problem. We do have a stockpile of vaccine of around 17 weeks. The aim was eventually to get that up to about a six months stockpile, but it is about 17 weeks at the present time. So the time for the company to renew its insurance is June 30th. So 17 weeks beyond June 30th, we have to have something accomplished or there will be danger of running out of the vaccine.

Mr. EARLY. Mr. Secretary, you know, it's like malpractice or product liability. We haven't been able to solve those things from day one, so I don't know if we are going to be able to do it in the area of vaccines. I wish you well, but I just hope we don't let that supply fall into a risky a situation.

Secretary BOWEN. Yes.

Mr. EARLY. And like everything else, I think this committee is ready to assist you on indirect costs if we can come up with some manageable type of number.

If we can get a percentage, a reasonable percentage, I think everyone would know what they can expect, and that is what the study said to do. It is just a question of the rates, what is acceptable and what is not. I think we have to look at that and I think we have to work together.

STABILIZATION OF GRANTS

One final thing on stabilization, Mr. Secretary. All I want you to do is look at that. We can say we want stabilization, but we have to get away from that roller coaster. Going back to that roller coaster type approach to grants and indirect and direct costs is bad policy. You know, we are hurting on trainees and we are hurting on intramural research in this particular budget.

All I want is your assurance that you are going to really look at that in depth.

Secretary BOWEN. In the issuing of the grants, I know that the NIH is carefully looking over young scientists and giving them opportunities, and they are utilizing the older scientists who have proved their productivity. As I mentioned this morning, the quality of our research directors is just superb.

Mr. EARLY. I do, too. Twenty years ago, Mr. Secretary, we funded 75 to 80 percent of the approved science. With last year's budget, most of the institutes were down to less than 30 percent. We are really not going in the right direction.

Secretary BOWEN. We don't dare to forget, though, that a great many more foundations and industries are increasing their research, too. The Hughes Foundation is spending $400 million or something like that on research.

Mr. EARLY. That was just fabulous. And if we get the privates to substitute, fine, but if they don't substitute, then you have to do it.

Thank you, Mr. Chairman.

Mr. NATCHER. Mr. Hoyer.

Mr. HOYER. Thank you, Mr. Chairman.

REDUCTIONS IN FORCE

Mr. Secretary, in response to the Chairman's question when he questioned you about FTE levels, do you have any expectation of having to have any RIFs within your department this year?

Secretary BOWEN. We anticipate no RIFs.

Mr. O'SHAUGNESSY. If the rescissions in certain programs such as health professions are approved, then associated with those rescissions there would have to be RIFs; otherwise, there would be none.

Mr. HOYER. In other words, am I correct that what you are saying is that if there were program terminations or substantial program reductions, you would not need the personnel, but just for fiscal reasons you don't need them at this point in time, RIFs this is?

Secretary BOWEN. That's right.

FEDERAL WORKER—TAX REFORM

Mr. HOYER. Mr. Secretary, you are very new and, therefore, may not have had an opportunity to know what effect, if any, this is going to have. The Congress adopted, as you know, a tax reform program in December—or the House, excuse me. The House document is now pending in the Senate. One of the provisions of that tax bill has a substantially adverse effect on individuals who are going to retire from the Federal service because of the nature of the kind of retirement system they have, that is, a contributory system.

It also adversely affects state, county and municipal teachers except in three states, who don't have contributory systems, and about 4 or 5 million private sector individuals who have contributory plans. As you may know, most plans in the private sector are noncontributory retirement plans.

Have your personnel people talked to you about any concerns about that bill which Congressman Frank Wolf and I have great concerns about because we think an awful lot of people in your Department probably at higher grade levels who have 30 years of service in and may be eligible to retire now will be forced out, costing the Federal Government some of the most talented individuals and financially costing us because of having to replace them while at the same time paying their retirement.

Has that problem confronted you?

Secretary Bowen. No, it has not, and I am not familiar with it, but I will make an inquiry as to the effect.

Mr. Hoyer. I would appreciate your looking at that, Mr. Secretary, because Congressman Wolf and I and others are working on it and we are very concerned that it is going to have quite an adverse effect throughout the Federal service in forcing, in effect, early retirements, or earlier than otherwise would occur. I should say eligible for retirement.

WIN PROGRAM

One last question. The WIN program is a program that my state department strongly supports and believes has been very effective, contrary to the information and reports you may receive. It has been suggested in the past that other Federal programs, Mr. Secretary, will make up for any loss of WIN funds.

Now, first of all, the WOI program, the Work Opportunities Initiative that you talked about. Is there additional monies planned for that or is this a coordination of existing programs?

Secretary Bowen. The WIN program would be phased out, and substituted for it would be the Work Opportunities Initiative, which would be funded with $200 million Federal money at a 50-50 matching basis with the states. That would make $400 million available, although it would be open ended, so that it could be more than $200 million, depending on what the states did.

Mr. Hoyer. What do we have in the WIN program now?

Secretary Bowen. It is a 90-10 match, and I don't know what the full number is but——

Mr. Hoyer. What is our Federal level?

Secretary Bowen. About $270 million in 1985; $220 million was appropriated in 1986. Coupled with the Work Opportunities Initiative program, though, is the Job Trainings Partnership Act, which can be combined with it to make both programs more effective.

Mr. HOYER. Mr. Secretary, I would appreciate your looking at that closely. You may even want to talk to Secretary Brock about it. In our state, for instance, the JTPA Title II program serves approximately 12,000 disadvantaged persons, which would be somewhat along the lines you are talking about. However, the eligible population is 400,000, according to our department, and that is a very, very small percentage to be served.

That is not to say that perhaps we have enough resources to serve everybody, but it is to say that we ought to be pretty careful when we are recommending going from $270 million in one program and replacing it with another of $200 million.

Secretary BOWEN. The $200 million, sir, would be open ended.

Mr. HOYER. Open ended to the extent that the states would supplement it, or the local governments?

Secretary BOWEN. That's right.

SOCIAL SERVICES BLOCK GRANT

Mr. HOYER. In Maryland, Mr. Secretary, the Social Services block grant supplements WIN in providing day care to 4,725 AFDC children, 45 percent of the 10,500 day care slots financed by Federal, state and local funds. This Federal grant obviously falls short of substantially meeting the need. That must be supplemented by large sums from the state and local government.

That is not necessarily wrong. It is to say, however, that as we retreat, as Gramm-Rudman hits, the resources in the states are simply not going to be available in many instances to take up the slack as they have been trying to do, and I know in my state of Maryland in many different programs.

In light of the fact you are new and, I know, will be analyzing these programs, I would hope that you would look at this example, which we can give you more pointedly, because I think it is probably not unique and that are simply not really maintaining current services—we are cutting.

The rhetoric that we are going to replace it with JTPA or other programs, particularly when you go from $275 million down to $200 million, and to simply say, well, the states are going to supplement this loss, I think, masks the fact that we are retreating in another area where the needs, as I pointed out, are great and we are meeting a very small percentage of that need.

Thank you, Mr. Chairman.

PLIGHT OF THE HOMELESS

Mr. NATCHER. Mr. Secretary, every resident of the District of Columbia is confronted almost every day with the tragedy of the homeless, many of whom are mentally ill, as we know. This is not only true here in the District of Columbia but also in most of the major cities throughout the United States. Both as a physician and as a public official, do you have any recommendation for dealing with this problem? What is the proper role of the Federal Government, Mr. Secretary?

We have this up from time to time before the committee, and we would like to hear from you.

Secretary BOWEN. The homelessness problem is a very difficult one with which to deal. Everyone has sympathy for the homeless, but I think we need to understand a few statistics before determining just what the remedy should be. First, a great many of the homeless, in my judgment, are mentally ill and have been released from mental hospitals too soon, as a result of both Federal and State initiatives, that try to get the individuals into the least restrictive environment to give them more freedom. But there hasn't been enough follow-up after their release.

A great many of them are also veterans. A great many are alcoholic and drug abusers. Some of them are there because of the loss of low cost housing facilities; some are there because they left home due to domestic violence; and I suspect crime also plays some part in it.

About two-thirds of them are single men. Twelve percent of them are single women. The tragedy is that 21 to 27 percent are families that are homeless. Forty-four percent are minorities, and the average age of them is 35. Only 10 to 15 percent are over 50, and only six percent are over 60.

The source of this information comes from the HUD report and from the National Conference of Mayors.

We have a lot of programs at the Federal level that can deal with the homeless. The problem is finding them, locating them and getting the services to them. For example, Medicaid is available, veterans services are available, many of our alcohol and drug abuse grants are available to help them.

The main emphasis should be on the local Governments to provide the type of housing that they need, and supplement it, with the Federal programs I have just mentioned. The SSI program, for example, is available. With only six percent over 60, that doesn't make too many of them eligible for Social Security unless they are disabled.

It is a tough problem. I think we need to reconsider the care of the mentally ill and reconsider whether some of them would not be much better off in our mental hospitals than they are on the street. We read the papers about some of these individuals. If you take them off the street if families take them in, they may be are back on the street again. I don't know how you cope with something like that.

RENTAL OF SPACE

Mr. NATCHER. Mr. Secretary, tell us if you will, how much do you have in your 1987 budget for the rental of space? How does this amount compare with the amount we had in the 1986 bill?

Mr. O'SHAUGHNESSY. Using the Office of the Secretary as an example, the cost per square foot is $22 a square foot compared to $16 and some cents for 1986. The cost per square foot varies between OPDIUS.

Mr. NATCHER. Do you have any control over the use of office space throughout the Department?

Mr. O'SHAUGHNESSY. Yes; we do control it in the sense that we can try to slim down our use of space. We have been trying to do that aggressively in the last few years. We have problems in that regard, particularly with medical facilities and critical facilities, such as Indian health facilities, that are not very amenable to change. For office space, we have been reducing the square footage. The price we are charged, however, is set by the General Services Administration.

Mr. NATCHER. Do the charges of the General Services Administration for space rental have any relationship insofar as the market rates or how much space is utilized?

Mr. O'SHAUGHNESSY. They try to look at the market in which the space is found and then charge what represents a fair market value in their view or something close to it.

Secretary BOWEN. I have some figures on that, if you want them.

Mr. NATCHER. Go right ahead, Mr. Secretary.

Secretary BOWEN. The Administration's objective is to reduce the office space level to the equivalent of 135 square feet per person. We have already been reduced in the Office of the Secretary from 205 square feet in 1984 to 144 square feet in 1987. The price per square foot in 1985 was $16.84 but in 1987, it is $22.44. It has gone up considerably. These rates are set by the General Services Administration. We are supposed to get down to the 135 square feet by 1988.

Mr. CONTE. Will you have vacant space after that? After you reduce everybody to 135 square feet.

Secretary BOWEN. There would have to be vacant space some place.

Mr. O'SHAUGHNESSY. It reverts back to the General Services Administration. They have other agencies that need space. They allocate it from there.

Secretary BOWEN. Agencies that are in leased spaces can come into these other spaces we are talking about.

Mr. CONTE. You could wind up with part of the Defense Department in HHS.

Secretary BOWEN. I suppose so.

LOW INCOME ENERGY ASSISTANCE

Mr. NATCHER. Mr. Secretary, you proposed in your budget the sum of $2.1 billion for fiscal year 1987 for low income energy assistance. During the last four months, however, the price of crude oil has decreased by about 50 percent. Does this play any part as far as the overall amount that you are requesting in the bill?

Secretary BOWEN. Our request was not based upon the recent reduction in the cost of oil. Hopefully, the price will remain down. I don't know anyone who can predict the price of oil a month from now or six months from now. I would feel safer, for the sake of the program, to keep it at the higher level. If we don't have to spend it, we won't, and it will revert back to the Treasury. I am glad to see it down; I hope it stays down.

Mr. NATCHER. For the record, if you will, supply your current estimate of the amount of funding necessary in fiscal 1987 to maintain the low income fuel assistance program at current service levels. Please place that in the record for us.

[The information follows:]

CURRENT SERVICES ENERGY PROGRAM

Based on price projections prepared by the Department of Energy (DOE) in January 1986, we expect that average cost of home energy to decrease by about two to nine percent from this winter to next. We expect to receive new projections from DOE in April and may be able to provide a better estimate to the Committee at that time.

There is a problem associated with trying to translate National decreases in energy costs to individual State levels. The allocation formula specified in the Low Income Home Energy Assistance Program's statute contains various provisions that tend to skew allocations in ways unrelated to increases or decreases in energy costs in each State. I am referring to the combination of the "hold-harmless" provision in section 2603(a)(2)(A)(ii) and the fact that we would revert to the pre 1985 formula (which was not based on the home energy costs of low income households in each State) if the appropriation drops below $2.1 billion.

These two factors result in some anomalous outcomes. Let me illustrate this with an example. As the following table shows home energy costs are expected to decrease by 5% in California, by 9% in Virginia, and by 15% in Maine, which relies heavily on home heating oil. (These changes are based on DOE projections from the fourth quarter of calendar year 1985 to the fourth quarter of calendar year 1986.) If the appropriation in FY 1987 were decreased to $2.01 billion (as happened this year under Gramm/Rudman/Hollings), Maine's LIHEAP allocation would not decrease at all, while California's would drop by almost 12%. If the appropriation declines further, e.g., to the CBO current services level of $1.919 billion in FY 1987, the results are even more disparate, as shown in the last column of the table.

	Percent change in home energy expenditures by low income 1985 to 1986	Percent change in allotment from $2.1 billion to $2.01 billion	Percent change in allotment from $2.1 billion to $1.919 billion
California	5	–12	–18
Maine	15		–3
Virginia	9	–4	–10

MEDICARE

Mr. NATCHER. Dr. Bowen, one of your areas of expertise is the Medicare program. With the enactment of the Prospective Payment System in 1983, this program has been fundamentally changed, as you well know. Your fiscal 1987 budget proposes almost $40 billion in Medicare reductions over the next five years. Many groups representing the elderly are concerned that these changes will result in lower quality care.

What impact have you seen to date from switching to the new system, if any, Mr. Secretary?

Secretary BOWEN. We have no solid evidence that there has been any reduction in the quality of care. You have isolated instances. The death rates have not gone up in the medicare age group, and that is in spite of the fact that the admissions have been lower and the length of stay has been lower.

To guard against any reduction in the quality of care, we do have our Peer Review Organization set up; their job is to monitor the quality of care and to make certain there isn't the "dumping" syndrome that we have heard about.

The PRO is to investigate all re-admissions to a hospital, within a week to determine whether or not patients were released too soon. Further, we have what we call a "Super PRO" which reviews the work and the quality of work of these PRO's.

Mr. NATCHER. Your 1987 budget proposes to reduce spending of special studies on quality of care from $11.2 million in 1986 to $7.1 million in 1987. How do you justify this reduction, Mr. Secretary?

Secretary BOWEN. The reduction would not be made were we not certain the work of this group would be continued. If it would meet with your approval, I would prefer to submit a written report on that.

Mr. NATCHER. That will be fine.

[The information follows:]

QUALITY OF CARE

The figures referenced are FY 86-FY 87 totals for a category of research projects entitled, "Program Analysis, Evaluation, and Quality of Care." Projects that typically fall under this category include:

Improvements to the existing Medicare and Medicaid data bases essential to providing information on health care expenditures and utilization patterns;

Evaluations of major changes in the Medicare program (other than the prospective payment system); and

Studies to determine the effects of program changes on the quality of care delivered to beneficiaries (especially the prospective payment system).

The FY 86-FY 87 funding level difference for this particular research and demonstration category does not represent a targeted reduction to special studies on quality of care, but rather a decline in amounts to be awarded to the data collection and program evaluation activities (other than the prospective payment system evaluations). All current quality of care projects will be continued in FY 1987 at their originally planned spending levels, and include the following:

Beneficiary impact study—An intramural study to detect possible PPS effects on the quality of care by analyzing the outcomes of hospital care on the health care status of the Medicare population, e.g., by analyzing mortality rates.

Hospital practice study—This study will measure the quality related effects of PPS by examining hospital usage and treatment patterns and their effects on inpatients and discharge status.

Non-intrusive outcome study—A long-term investigation into the feasibility of using Medicare administrative data to detect and monitor quality of care levels within individual hospitals for specific medical conditions.

ESRD study—This study focuses on the issue of whether the Medicare ESRD hospitalized patients, as a high cost treatment population, is being adversely affected by PPS.

Clinical analysis of PPS impacts on th quality of inpatient medical care—an in-depth clinical analysis of PPS effects on the quality of inpatient care. It will evaluate PPS impacts on quality by assessing potential treatment patterns, and resultant health status through a thorough examination of the medical record.

Indexes of hospital efficiency and quality—A study designed to produce a method for evaluating the relationship between quality and efficiency levels within hospitals, useful in measuring the combined effects of PPS.

Health status at discharge—This project is intended to develop and standardize a method for determining Medicare patients' health status at the time of hospital discharge by assessing physical and mental functions and post-discharge treatment needs.

The above study dealing with the appropriateness of post-discharge services is currently being pilot tested. Pending the results of this preliminary analysis, a national study may be desirable.

HOSPITAL PAYMENTS

Mr. NATCHER. The current freeze on hospital payments has caused many in the health care industry to worry that the Medicare program is abandoning its concept of paying a fair price and instead switching to paying what the trust funds can afford.

What is your reaction to this criticism?

Secretary BOWEN. The law outlines the process; it is a very technical process for updating the Diagnosic Related Groups. It was this process that the Department used to determine that the fiscal year 1985 rates should not be increased in 1986. The law required that certain factors be considered in updating the rates.

These factors were: the market basket for hospital inflation or any increases in hospital inflation; any corrections for previous forecasting errors; and adjustments due to productivity or technology and effectiveness. Of course, we have the propac which study the whole situation and then makes its recommendations.

Just to give an example, for the Prospective Payment System fiscal year 1986 update, the market basket was a 4.2 percent increase whereas the correction of previous forecast errors was a negative 1.2. There is a negative one percent increase in productivity due to the decrease in the length of stay—actually, the decrease in the length of stay is a positive event. There was a 1.5 percent increase for technology. The effectiveness due to shifts to out-patient from in-patient was a negative two. A negative six was for increases in the case mix due to improved coding—that is as opposed to more complex cases.

This all totaled to a negative 4.4 percent, and due to the concerns about the impact of a reduction of 4.4 percent, the fiscal year 1986 update was zero. There was no change. Sometime before June 1st, we will be setting the 1987 rates. It has to be through a formula such as I just mentioned. That formula was set by law, as I understand it.

Mr. NATCHER. Mr. Conte, I yield to you.

DEPARTMENTAL BUDGET REQUEST

Mr. CONTE. Dr. Bowen, when you started your presentation, you said the proposed departmental budget for 1987 totals $345.6 billion, which is $12.7 billion more than the 1980 budget, $30 billion more than the HHS budget for 1985 and since 1981, the Department's budget has increased by $116.8 billion.

Anybody looking at that would say this Committee has gone completely ape here. I had my staff give me the entitlements and discretionary. You would find that the budget in 1981 is almost the same budget that we have at the present time. In 1981, we had $12,812 million, and this year, after Gramm-Rudman, we wind up with $13,671 million, an increase over that period of time of about $859 million in what we could control.

Secretary BOWEN. About 96 percent of our budget is entitlement program and four percent for discretionary programs. That is one reason for such tough choices in making these decisions.

REDUCTION IN SSA EMPLOYMENT

Mr. CONTE. Last year there was a great deal of discussion about an OMB initiated plan to reduce SSA employment by 17,000 over a five year period. I believe that schedule is going to begin this year. I see the budget proposal will reduce SSA employment by another 2,000 positions.

Is that part of that five year plan to reduce employment by 17,000?

Secretary BOWEN. Could I ask Mr. Sabatini to respond?

Mr. CONTE. Yes, indeed.

Mr. SABATINI. We still have the overall target of reducing total employment by about 20 percent by 1990. We are proceeding on a year-by-year basis in making these reduction—proceeding very, very cautiously, making sure the reductions reflect improved processes and improved productivity and are not at the expense of the quality or level of service we are delivering.

Mr. CONTE. Did you read our House Report last year?

Mr. SABATINI. Yes, sir.

Mr. CONTE. We said that before we approve any further reductions in staff we expected to receive a well thought out and well documented analysis of manpower needs from the agency. The Department states in its justification that the analysis is contained in the justification. However, in looking through the justification, there is no mention of any year beyond 1987. I further note your use of overtime in fiscal year 1987 would double.

How can we approve this massive reduction without knowing what road you are going down here? It would seem to me that any analysis would have to present the long term five year picture you are talking about, so that we could look at it.

Mr. SABATINI. The overall five year plan, Mr. Conte, is a general target in the direction we are moving. We have not asked that target be approved. What we have said is, this is the direction we think we should move through improvements in productivity through our system's organization efforts—that we can reduce overall staffing by 20 percent and still maintain a level of service that is as good as or better than what we have traditionally given.

We are saying that each year we will be presenting that increment of that year's target with all the details. I think the staffing analysis referred to in our justification on pages 182 through 193 shows that the reductions we have made in concert with this plan, thus far have been made without any deterioration to service. We will, at the end of this year, be approximately 8 percent smaller in terms of FTE utilization than we were five years ago.

By the same token, by every indicator and every measure we have, which will be reflected in the report coming to the Committee shortly, the quality and level of service we are delivering is as good today or better than it has ever been.

Mr. CONTE. But does it make sense to get rid of all the employees and then have overtime doubling?

Mr. SABATINI. We're making the reductions in a very consistent phasedown way, so that we can avoid any kind of RIF, furlough, or layoff. To meet cyclical work loads from time to time, we feel it is better to utilize overtime than to bring people on board that will eventually not be needed. We want to do everything possible before a RIF in the agency. We're committed to that, and we're convinced that we can do it.

PROSPECTIVE PAYMENT SYSTEM

Mr. CONTE. We'll ask more questions on this later on.

In 1983, Congress instituted the Medicare prospective payment system as one way of helping to hold down overall health costs. Almost since its inception, however, we've been hearing that the program is working to send patients home quicker and sicker.

Many groups have looked into this problem, including GAO and even your Inspector General, and they all seem to reach basically the same conclusion.

What are your thoughts on this situation, Doctor? Is it a problem of abuse of the system, or is it actually the system itself?

Secretary BOWEN. "Quicker and sicker" discharges are certainly the furthest from our desire, but there are going to be instances of that no matter how perfect the program is. Patients occasionally sign themselves out, or patients are much improved and then, for one reason or another, develop a complication or a setback and have to be readmitted. And so there are some instances that are beyond the control of the hospital or the physician.

Our answer in trying to prevent that from happening is our monitoring system through the PRO or the Peer Review Organizations. They have strict rules that they must follow. They may not have enough power to correct some of the deficiencies, but they are doing a good job of calling errors to the attention of the hospital and the physicians. If the errors are repeated in certain institutions, then the PRO takes action through HCFA.

Mr. CONTE. Well, beyond any of these problems, nobody is doubting that fact that prospective payments have lowered the cost of Medicare, no doubt about that. In fact, in some cases, it has been quite dramatic.

Don't you think that we should be putting some of those savings into a program like home health as a way of making sure that patients are adequately cared for and maintained after they leave the hospitals?

Secretary BOWEN. That's something that needs to be investigated and thought out. Certainly no one wants an individual to receive less than the most adequate care. Home-based care, however, is growing very rapidly—in fact, it is the most rapidly growing area of the whole program. It's growing so fast that one has to look into it to make sure that it isn't being abused. We are making some studies on that.

It's growing eight times as fast as any other phase of the program.

Mr. CONTE. Well, that's encouraging.

ENERGY ASSISTANCE

Doctor, you don't have to answer this now. You can get it for the record. What is the Department adjustment for the number of people eligible for Low Income Energy assistance who are currently being reached by the program, and what percentage of the average cost of heating a home is covered by this assistance? What are the Department's latest figures with respect to the number of people who had their utilities shut off for failure to pay their heating bills, even with the availability of the energy assistance?

You can give all those for the record.

[The information follows:]

ENERGY PROGRAM

In fiscal year 1986, States estimate that they will provide assistance with heating costs to 7.3 million households. (This estimate was made prior to sequestration.) In fiscal year 1984, the latest year for which we currently have data, approximately

23.4 million households (or 27 percent of all U.S. households) were eligible for the program according to the statutory maximum criteria (the greater of 150 percent of the poverty level or 60 percent of State's median income). However, a majority of States use eligibility criteria that are more restrictive than the statutory maximums. Using State eligibility criteria, we estimate that 17.6 million households are eligible for energy assistance. Thus, in fiscal year 1986, States will serve about 41 percent of those households eligible according to the more restrictive State criteria.

In fiscal year 1986, the average benefit for heating costs, including crisis assistance, will offset about 45 percent of the average heating cost incurred by the LIHEAP recipient household.

There are no reliable national estimates of the number of households who had their utilities shut off because of inability to pay. Two national surveys indicate that 1.3 to 1.4 million households were without heat for one or more days in the winters of 1981-1982 and 1983-1984 because of their inability to pay fuel bills.

NATIONAL COMMISSION ON ORPHAN DRUGS

Mr. Conte. Last year, Doctor, Congress passed an authorization for the National Commission on Orphan Diseases. It has come to my attention that the Department has yet to name the individuals to serve on that commission.

Do you anticipate making those appointments?

Secretary Bowen. I didn't get the name of the——

Mr. Conte. The Orphan Disease Commission.

Secretary Bowen. I'll have to ask for help on that. I don't know.

Dr. Macdonald. We have expedited those appointments, and we should be shortly naming the members of the commission.

Mr. Conte. What do you mean by shortly?

Dr. Macdonald. Next week.

Mr. Conte. Sounds pretty good.

NEW WIN PROGRAM

I'm told that many aspects of the new proposal to supplement WIN are not at all compatible with the Massachusetts program. For instance, the Massachusetts program relies heavily on using educational resources as necessary to provide the qualifications to obtain work, and I understand your proposal would not allow education to qualify as being hard work. I am also told that you require states to achieve working status for up to 75 percent of the AFDC recipients with children over six, while the ET program relies on voluntary work and has achieved substantial success with those with children under six, which it would not be able to count toward the 75 percent mandate.

I take it there are some problems then in your assertion that Massachusetts could simply switch over to the AFDC proposal on its current WIN demonstration program. Have you looked at that?

Secretary Bowen. Yes, we have made some comparisons, and we don't feel that the Massachusetts program will be handicapped at all. They are spending, about $40 million a year on the program; $8 million of this has come from WIN, and $32 million has been from the State's own funds. So they can continue essentially all of their activities.

Our program has a little more clout to it. Instead of just having paper registration, it actually mandates that within the first year, 25 percent of the participants be in an actual Job Search or job training programs, at the end of the second year 50 percent, and at the end of the third year 75 percent. Those are targets that are attainable.

Mr. CONTE. Under your program they would get the same $8 million, right?

Secretary BOWEN. It's an open-ended program; so whatever they would want, they can fund. In addition, they can utilize the JTPA program.

Mr. CONTE. Thank you, Mr. Chairman.

Doctor, I might add that Joe says he's been up here under five Secretaries, and I've been up here under twelve Secretaries. You've only been here since December, and I was a little worried about your coming up here, but you've done the best job of any Secretary we've ever had here.

Secretary BOWEN. Sir, you weren't as worried as I was. [Laughter.]

Mr. CONTE. You did a good job today. Didn't he, Mr. Chairman.

Mr. NATCHER. Yes, I agree with you, Mr. Conte. He certainly has.

And, Mr. Secretary, both Mr. Early and Mr. Conte were in Massachusetts when I arrived. [Laughter.]

Mr. Early, I yield to you.

PEER REVIEW

Mr. EARLY. Just a couple of questions.

Dr. Bowen, in your position at the Indiana School of Medicine, did you have any concerns when you were there about peer review or any other type of thing that you now want to try to correct?

Secretary BOWEN. Well, frankly, I was not in that particular area. I was in the Department of Family Medicine and was the head of medical education for students who were interested in going into family medicine.

Mr. EARLY. Well, in family medicine, did you think that the Federal government should expand their role in that? That's really where it is, as far as I'm concerned, and I think our public schools put out a lot more emphasis on family medicine.

Secretary BOWEN. Well, obviously I'm a little prejudiced toward the family medicine program. I do think that in the area of primary care and family medicine, especially as we head toward the competition and capitation type programs that eventually are coming. We need more of the family medicine and primary care physicians.

COST OF MEDICAL SCHOOLS

Mr. EARLY. A year ago, Doctor, I spoke at a reunion of the Massachusetts Medical School alumni, which is only about twelve years old. The school doesn't have that many graduating classes, probably an alumni of 500, but I was extremely impressed with the students that graduated from the University of Massachusetts Medical School. You know, they had a tuition that they could afford. Many went into family practice. They went into the underserved areas. They had stayed in Massachusetts, which was one of the intents. They were family medicine people, and they weren't making a ton of money.

They weren't having quite the problem with malpractice and that type of insurance that others do. They were really going in the right direction. The people were being served more. And I really hope that you do pursue continuing the family medicine program.

Secretary **Bowen**. Well, I think the quality of the incoming medical student is superb. In fact, as an example, at Indiana University, the grade point average of the freshman medical student, after four years of pre-medical work, was 3.7 out of a possible 4.0. Now that's an A-minus. And as Governor, one of my toughest jobs was to answer letters from irate parents whose children had, we'll say, a 3.3, which is still a very good grade, and still weren't able to get in. So the quality is there, and I think that the attitude has changed. I hope that more of them will continue into that area, although percentagewise it hasn't made much shift.

Mr. **Early**. It's hard, though, Mr. Secretary, to go into it if you go to Boston University, Harvard and Tufts, and you get committed to over $100,000 in expenses over four years. You can't make that money back. And if we leave them with a debt on their loan programs, you know, the family medicine person won't get real rich. It's tough.

My final question, in your role as Governor, Mr. Secretary, did you have any objectives that you'd now like to see your Department address?

Secretary **Bowen**. As Secretary, you mean? My first thought is that in 1975 we were able to put through a model malpractice law. I don't mean that the Federal Government should immediately jump into that; but I think that we need to study the role of the Federal Government in what we do to at least stimulate the States to develop proper malpractice laws. That relates to the practice of defensive medicine which makes the costs rise and which can increase the tuition rates.

That would be the first carryover that comes to mind. "Service with courtesy"—that is one of the things that we tried to stress. I think that made our Administration effective. I think we have a good start here; the staff of our Department—I have been immensely impressed—and I think we're going to have that same type of effective Administration here.

Mr. **Early**. There's a lot of talent down there.

AUTONOMY OF HHS

And what is your opinion on this matter of infringing on autonomy? What is your personal observation or opinion on autonomy, let's say at NIH?

Secretary **Bowen**. Well, I recognize the need for both holding expenses down and keeping access and quality up. Sometimes that will put me at odds with the OMB, but once again, I intend to voice my opinion. I may not always get my way, but I'm sure that I can be influential in helping to develop some of the programs that we all think are necessary.

I'm not complaining, because I knew about this before I got here, but when 96 percent is spent on entitlement and only 4 percent is discretionary, and we've got to cut, that doesn't leave us very much room.

Mr. **Early**. I'm very impressed with you today, Mr. Secretary. Thank you.

Secretary **Bowen**. You're very kind. Thank you.

CONSOLIDATION OF AIDS FUNDING

Mr. **Natcher**. Mr. Secretary, your 1987 budget proposes to consolidate all funding for activities relating to Acquired Immune Deficiency Syndrome in the Office of the Assistant Secretary of Health.

Do you have a plan for the use of these funds?

Secretary **Bowen**. The funds will be apportioned by the same method as they have been before. It puts it all under the supervision of one individual, Dr. Dowdle, so that we can have one spokesman, one organizer, and one person in charge, so that we will get a real, coordinated effort in this.

Mr. **Natcher**. How much of the money appropriated for AIDS activities for 1986 are you proposing to rescind? What is that amount?

Secretary **Bowen**. I believe it's $41 million.

Mr. **Natcher**. $41 million.

Secretary **Bowen**. These funds were over and above what could effectively have been utilized. Certainly I believe we should spend the funds, if there is a place where they could effectively be utilized, but all the areas of research that need to be covered are essentially covered.

Mr. **Natcher**. Mr. Secretary, if you would insert in the record at this point a table showing AIDS funding by agency and account from 1982 through 1987, and if you will, include separate columns for sequestration and proposed rescissions in 1986.

[The information follows:]

PUBLIC HEALTH SERVICE
ACQUIRED IMMUNE DEFICIENCY SYNDROME

(DOLLARS IN THOUSANDS)

AGENCY:	FY 1982 Actual	FY 1983 Actual	FY 1984 Actual	FY 1985 Actual	FY 1986 Approp.	FY 1986 Sequest.	FY 1986 Rescind	FY 1986 Estimate	FY 1987 Request	TOTALS
CDC................	$2,050	$6,202	$13,750	$33,298	$64,925	$2,792	$11,848	$50,285	($45,409) c/	$150,994
NIH................	3,355	21,668	44,121	63,737	140.723	6,051	13,915	120,757	(142,990) c/	396,628
ADAMHA.............	0	516	2,791	2,578	12,704	546	0	12,158	(13,733) c/	31,776
AIDS Coordination..	---	---	---	---	---	---	---	---	(1,350) c/d/	1,350
OASH...............	---	---	---	---	---	---	---	---	203,482 e/	(203,482) c/
HRSA...............	---	---	---	---	16,000 a/	688	15,312	0	---	---
Total Labor, HHS...	$5,405	$28,386	$60,662	$99,613	$234,352	$10,077	$41,075	$183,200 b/	$203,482	$580,748

a/ Appropriated to the office of the Secretary to fund four demostration projects on the delivery of health care services to victims of AIDS.
b/ Estimate for FY 1986 reflects effects of G-R-H reductions of $10,077 & rescission of $41,075.
c/ Non-adds. Reflects current allocation plans for distribution of AIDS resources.
d/ Provides $350 for PHS AIDS Coordinator and support staff, and $1,000 for expansion of the National AIDS Public Information Campaign.
e/ The Administration is proposing that funds(appropriated by the Labor, HHS committee) for AIDS research be requested in a new account to be established in OASH.

*NOTE: Does not include funding for the Food and Drug Administration.

Mr. Natcher. Mr. Secretary, I have a few additional questions as do other members of the subcommittee that will be submitted to you. I know you will give us good answers for the record. Mr. Secretary, we want to thank you for your appearance before our Committee at this time. As we know, this is your first appearance and this has been a good hearing, Mr. Secretary. We are pleased to have you.

Secretary Bowen. Thank you very much for your kindness.

Mr. Natcher. Thank you very much. The Committee will now adjourn until 10:00 a.m. in the morning.

[The following questions were submitted to be answered for the record:]

Unauthorized Programs

Mr. Natcher: Insert in the record at this point a list of all current HHS activities not authorized for FY 1987 with the amount of the 1986 appropriation and the 1987 budget request for each activity?

Secretary Bowen: The budget request for fiscal year 1987 includes amounts for programs for which legislation has expired:

	(In thousands) FY 1986 Enacted to Date	FY 1987 Request
Public Health Service		
Health Resources & Services Admin. National Health Service Corps......	[illegible]	$46,996
Office of the Asst. Secy. for Health Adolescent Family Life...............	14,853	14,722
Social Security Administration		
Low Income Home Energy Assistance....	2,100,000	2,100,000
Office of Refugee Resettlement........	347,801	372,996
Office of Human Development Services		
Human Development Services		
Head Start, ACYF......................	1,067,059	1,075,059
Native American Programs..............	27,300	27,300
Public Health Service		
Health Resources & Services Admin. Primary Care Block Grant*............	591,300	565,100

*In addition, legislation is being requested to consolidate the Community Health Centers, Black Lung Clinics, Migrant Health, and Family Planning programs into the Primary Care Block Grant. Of these programs only the Black Lung Clinics program has authorizing legislation.

The Health planning activities, for which there is no request in the fiscal year 1987 budget, were funded in fiscal year 1986 and lack legislation in fiscal year 1987.

Grace Commission

Mr. Natcher: Insert in the record at this point a summary of the Department's activities to date in meeting savings targets identified by the President's Private Sector Survey on Cost Control (Grace Commission).

Secretary Bowen: A summary of implementation of Grace Commission recommendations follows:

o The Grace Commission made approximately 300 recommendations directly relating to HHS.

o We have implemented or are implementing approximately 90 percent. Of the remainder, most are under study or require action by some other agency.

o Some examples of the recommendations implemented or being implemented are:

-- The Commission recommended HHS transfer the Work Incentive program from HDS to SSA. Not only have we proposed legislation to do this, but to make more fundamental reforms to ensure that States operate effective job search and employment programs for welfare recipients, saving $150 million in fiscal year 1987.

-- The Commission recommended that we adopt a prospective payment system for hospitals, and take other actions to control health care costs. We have implemented the former and have included in this budget legislative and regulatory proposals saving $6 billion in Medicaid and Medicare.

-- We are implementing the Commission's recommendation to carry out rapidly systems modernization in SSA. We expect to save 17,000 FTEs between fiscal year 1984 and fiscal year 1990, principally due to increases in productivity.

o We established a review process to ensure implementation of the Commission's recommendations, and to monitor those not yet implemented--including White House and OMB review. We will continue to track progress on all recommendations not fully implemented.

o Implementation of the recommendations thus far has resulted in savings of over $22 billion between fiscal year 1984 and fiscal year 1986, and a projected fiscal year 1987 savings of over $14 billion. These savings are estimates in a similar fashion as did the Commission.

Legislative Proposals

Mr. Natcher: Insert in the record at this point a list of all legislative proposals submitted as part of the fiscal year 1987 budget, and give the status of each.

Secretary Bowen: Several accounts have legislative proposals included in the budget request. The proposals are listed below:

	Dollars in Thousands
Health Care Financing Administration	
Medicaid	
Cap medical assistance payments...	-882,000 1/
State & local admin. cost freeze..	-260,000 1/
36 mo. all RCA/RMA refugee prog...	-30,237 1/
Total, Medicaid.................	-1,172,237
Program Management (Medicare Contractors)	
Contractor processing of RRB claims (Trust funds).............	(-2,000) 1/
Medicare contractor initiative (Trust funds).....................	(-2,800) 1/
Total, Prog. Mgmt Trust Funds...	(-4,800)
Social Security Administration	
Assistance Payments (AFDC)	
Reform welfare administration.....	-15,000 1/
Workfare benefits.................	-252,000 2/
Workfare administration...........	+200,000 2/
End parents' benefit-essential person limit......................	-101,000 2/
Limit assistance to minor mothers not living with parents...........	-20,000 2/
36 mo. all RCA/RMA refugee prog...	-48,742 1/
Total, Assistance Payments......	-236,742
Office of Refugee Resettlement	
36 mo. all RCA/RMA refugee prog.....	+78,979 1/
Office of Human Development Services	
Family Social Services	
Medicaid eligibility..............	-38,690 2/
	=========
Total, Health & Human Services L/HHS..	-1,368,690

1/ Waiting for final clearance from the Office of Management and Budget (OMB).

2/ Pending in both Houses of Congress.

Borrowing Authority

Mr. Natcher: The various appropriations for public assistance accounts include language which allows the department to cover any unanticipated shortfalls at the end of the fiscal year. The fiscal year 1987 budget indicates that this language is being used as a routine substitution for supplementals when initial estimates are off or when the President's budget is not enacted. First why were supplementals not requested to cover your current $1.7 billion shortfall in the public assistance accounts? Second what is your general view of the purpose of the so-called borrowing authority language in these accounts?

Secretary Bowen: Actual expenditures for entitlement programs depend on eligibility criteria set up in authorizing statutes.

During the last several years, the Department has had the authority to drawdown funds from the subsequent year's appropriation, a procedure requiring complicated bookkeeping and confusing the accounting between different fiscal years. The new language, amended in 1986, permits the open-ended use of funds within the same fiscal year as long as eligibility criteria are met.

Thus, instead of borrowing from the subsequent year and requesting an increase later to cover that amount, the funds are drawn from the Treasury and recorded as budget authority in that same year.

It seems unnecessary to request a supplemental, when current language enables the use of funds to cover shortfalls. I think the language change proposed will increase efficiency and eliminate complicated and confusing accounting of funds.

Entitlement Programs

Mr. Natcher: In some cases, your 1987 budget assumes savings in entitlement programs which are based on legislative proposals. Please give us a list of these, together with the amounts required for these programs in 1986 and 1987 under current law.

Secretary Bowen: Several accounts have legislative proposals included in the budget request. The proposals are listed below with current law funding estimates:

	(In millions) FY 1986	 FY 1987
Health Care Financing Administration		
Medicaid..............................	$23,398	$25,880
Program Management		
Program level.......................	(1,202)	(1,253)
Federal Funds.......................	85	89
Social Security Administration		
Assistance Payments (AFDC)........	8,953	8,440
Office of Refugee Resettlement........	322	379
Office of Human Development Services		
Family Social Services..............	788	897

In addition, one discretionary program includes a legislative proposal:

Office of Refugee Resettlement........	342	379

Section 515 Reserves

Mr. Natcher: Insert in the record at this point a list by activity and account of all funds "reserved" or withheld from obligation under the authority of section 515 of the Treasury, Post Office Appropriation Act for FY 1986.

Secretary Bowen: The following amounts have been withheld from obligation in accordance with Section 515 in those programs that are reviewed by the Subcommittee:

	Dollars in Thousands
Public Health Service	
Health Resources & Services Administration...	$285
Centers for Disease Control..................	471
National Institutes of Health................	4,056
Alcohol, Drug Abuse, & Mental Health Admin...	1,170
Office of the Assistant Secy for Health......	529
Total, Public Health Service................	6,511
Health Care Financing Administration	
Program Management	
Program level................................	(579)
Federal funds................................	213
Social Security Administration	
Assistance Payments..........................	195
Limitation on Administrative Expenses........	266
Total, Social Security Administration......	461
Office of Refugee Resettlement.................	100
Child Support Enforcement......................	117
Office of Human Development Services	
Human Development Services...................	423
Family Social Services.......................	145
Total, Office of Human Development Svcs....	568
Departmental Management	
General Departmental Mangement...............	160
Office of the Inspector General..............	276
Total, Departmental Management.............	436
	=====
Total, Department of Health & Human Services...	8,406

General Provisions

Mr. Natcher: Please insert in the record at this point an explanation of each change in General Provisions which you are proposing for the 1987 bill.

Secretary Bowen: The General Provisions with explanations of changes follow:

Introduction

The President's budget for fiscal year 1987 includes recommendations regarding changes to the General Provisions of the proposed Labor/HHS/Education and Related Agencies appropriation bill. General Provisions proposed by the Department are included in the Appendix of the 1987 budget,
Part I, at the conclusion of the schedules for the Department of Health and Human Services (title II general provisions) and the Department of Labor (title V general provisions).

The fiscal year 1987 General Provisions language is based on Public Law 99-178, making appropriations for the fiscal year 1986.

The following is a listing and explanation of the proposed changes:

Title II

Section 202. Funds appropriated in this Act for the Alcohol, Drug Abuse, and Mental Health Administration and the National Institutes of Health shall be used to support no fewer than [6,100 new and competing] 19,400 research projects grants.

Explanation

This provision has been revised. The 1987 budget request is based on achievement of a policy to fund 18,000 research project grants at NIH. It is through these grant programs that individual scientists and scientific institutions are able to respond rapidly to emerging areas of scientific promise.

The identification of a policy objective for research projects that focuses on the total number of awards, rather than only the number of new and competing projects, recognizes the full portion of resources available in this funding mechanism. Growing fiscal pressures throughout the Federal budget demand that a level of stability be achieved in project grants that does not result in large fluctuations in resources for other research support mechanisms. In addition to the stability policy for managing resources, the NIH will also devote greater cost consciousness in the review and approval of project proposals.

A principal element in the ADAMHA request is the support of 1,400 investigator-initiated research project grants. Maintenance of this level in 1987 will provide continued reasonable development of the alcohol, drug abuse, and mental health research community.

Section 205. Appropriations [in this Act for the Health Resources and Services Administration, the National Institutes of Health, the Centers for Disease Control, the Alcohol, Drug Abuse, and Mental Health Administration, the Office of the Assistant Secretary for Health, the Health Care Financing Administration, and Departmental Management] shall be available for expenses for active commissioned officers in the Public Health Service Reserve Corps and for not to exceed two thousand four hundred [and fifty] commissioned officers in the Regular Corps; expenses incident to the dissemination of health information in foreign countries through exhibits and other appropriate means; advances of funds for compensation, travel, and subsistence expenses (or per diem in lieu thereof) for persons coming from abroad to participate in health or scientific activities of the Department pursuant to law; expenses of primary and secondary schooling of dependents in foreign countries, of Public Health Service commissioned officers stationed in foreign countries, at costs for any given area not in excess of those of the Department of Defense for the same area, when it is determined by the Secretary that the schools available in the locality are unable to provide adequately for the education of such dependents, and for the transportation of such dependents, between such schools and their places of residence when the schools are not accessible to such dependents by regular means of transportation; expenses for medical care for civilian and commissioned employees of the Public Health Service and their dependents, assigned abroad on a permanent basis in accordance with such regulations as the Secretary may provide; rental or lease of living quarters (for periods not exceeding five years), and provision of heat, fuel, and light and maintenance, improvement, and repair of such quarters, and advance payments therefore, for civilian officers, and employees of the Public Health Service who are United States citizens and who have a permanent station in a foreign country; purchase, erection, and maintenance of temporary or portable structures; and for the payment of compensation to consultants or individual scientists appointed for limited periods of time pursuant to section 207(f) or section 207(g) of the Public Health Service Act, at rates established by the Assistant Secretary for Health, or the Secretary where such action is required by statute, not to exceed the per diem rate equivalent to the rate for GS-18; not to exceed $9,500 for official reception and representation expenses related to any health agency of the Department when specifically approved by the Assistant Secretary for Health.

Explanation

A portion of this provision, indicated by the brackets, is deleted in order to simplify the language.

This provision has been revised to decrease the limitation on the number of regular commissioned officers in the Public Health Service Commissioned Corps from 2,450 to 2,400. The decrease represents the level of regular commissioned officers compatible with program requirements of the Public Health Service and consistent with current membership in the regular commissioned corps.

Section 206. No funds appropriated for the fiscal year ending September 30, [1986] 1987, by this or any other Act, may be used to pay basic pay, special pays, basic allowance for subsistence and basic allowances for quarters of the commissioned corps of the Public Health Service described in section 204 of title 42, United States Code, at a level that exceeds 110 percent of the Executive Level I annual rate of basic pay: Provided, That amounts received from employees of the Department in payment for room and board may be credited to the appropriation accounts "Health Resources and Services","National Institutes of Health Office of the Director", "Disease Control", and "Federal Subsidy for Saint Elizabeths Hospital": Provided further, That funds appropriated by this Act or any other Act shall not be used for special, revised special, or continuation pay to any physician or dentist appointed to the Public Health Service Comissioned Corps during the current year whose primary duties are determined by the Secretary to be administrative or managerial: Provided further, That any physician or dentist who, through promotion or reassignment within the Corps, assumes as primary duties administrative or managerial responsibilities may, at the discretion of the Secretary, receive such special, revised special or continuation pay.

Explanation

An important mission of the Public Health Service is the provision of direct care services to patients at service facilities. To insure an adequate supply of physicians and dentists, the Corps is authorized to pay bonuses to these two medical specialties. This provision would permit physicians and dentists in direct-care settings to continue to receive such bonuses. In addition, the provision recognizes that in many cases, direct-care facilities or programs are best administered by experienced Commissioned Corps officers. Accordingly, this provision permits continued payment of bonuses to physicians and dentists who are promoted to administrative or managerial positions. However, a recent HHS IG report described several instances in which Commissioned Corps officers had been assigned to managerial-type positions in non-direct care facilities or programs. Thus, to insure that the Commissioned Corps continues to focus on the provision of direct-care services, and that Corps administrators are experienced in Corps-provided services, this provision also prohibits the payment of bonuses to physicians or dentists whose first Corps assignment, made during FY 1987, is primarily administrative in nature.

[Section 211. Pursuant to section 264 of title 42, United States Code, funds provided in this Act for research into the causes and transmission of the acquired immune deficiency syndrome disease may be used by the Surgeon General for closing or quarantining as a public health hazard any bathhouse or massage parlor which in his judgment pursuant to law can be determined to facilitate the transmission or spread of the AIDS epidemic].

Explanation

This provision is deleted.

The Department already possesses this authority through Section 361 of the Public Health Service Act which authorizes the Secretary to take such measures as are necessary to control the introduction, transmission, or spread of communicable diseases. With regard to this activity, the Public Health Service normally works through State and local authorities to accomplish the desired results.

Section 211. Funds appropriated by this Act may be used to pay bonuses, as authorized under 5 U.S.C. 5948, only to those persons who are licensed to practice medicine except that this provision shall not apply to individuals receiving such bonuses prior to January 1, 1987.

Explanation

Under current law, the Department may pay physician comparability allowances to general schedule physicians in specialties having significant recruitment and retention difficulties, even if the physician is no longer licensed to practice medicine.

The intent of this provision is to prohibit payment of physician bonuses to unlicensed physicians. No physicians receiving such bonuses prior to January 1, 1987 will be affected by this provision.

Section 212. Not to exceed one-half of one percent of appropriations made available for this fiscal year for the activities of the National Institutes of Health funded in this Act may be transferred to any other appropriation for the National Institutes of Health, but no such appropriation, except as otherwise provided, shall be increased or decreased by more than one per centum by any such transfers and Congress shall be notified promptly of any such transfer: Provided, That research grants or contracts funded by any appropriation made to any National Institute of Health or the Alcohol, Drug Abuse, and Mental Health Administration, shall be awarded only after consideration by the advisory body of the full cost of such a research grant or contract.

Explanation

Consistent with a recommendation made in the IOM study of NIH, Responding to Health Needs and Scientific Opportunity: The Organizational Structure of the National Institutes of Health, October 1984, this provision would authorize the transfer of funds between appropriations to the National Institutes of Health (NIH). This authority would enable NIH components to either contribute or receive funds from each other in order to quickly respond to national health emergencies requiring NIH expertise. In the past, when biomedical crises, such as Acquired Immune Deficiency Syndrome, required prompt action, the NIH could not react without prior authority from the Administration and Congress to redirect funds to urgent problems.

The provision also would require advisory groups to NIH and the Alcohol, Drug Abuse, and Mental Health Administration to take into account the indirect costs as well as the direct costs of research grants and contracts when deciding on their funding status.

Section 213. Funds appropriated under this title shall not be available for increases to State and local governments' allocated overhead rates above the rates in effect on September 30, 1985.

Explanation

This provision would preclude increasing the proportion of Federal funds for overhead purposes. It does not require State and local governments to reduce from current overhead spending rates.

In most discretionary programs, overhead increases often result in a one-for-one reduction in funds available for programs or program services. In entitlement programs, when this one-for-one relationship does not exist, additional Federal funds diverted to State and local overhead costs add to the Federal deficit and increase the pressure to reduce programs. This provision will help ensure that funds appropriated under this title are used as intended for programs, not for overhead. We want at least the same proportion of Federal funds to go to the programs as did during FY 1985.

Section 214. Notwithstanding 31 U.S.C. 1348, and for the purpose of insuring proper management of federally supported computer systems and data bases, funds appropriated by this Act are available for the purchase of dedicated telephone service between the private residences of employees assigned to computer centers funded under this Act, and the computer centers to which such employees are assigned.

Explanation

This provision would allow the Federal government to cover the cost of dedicated data lines in residences of selected professional computer specialists and other staff who are responsible for monitoring, and if necessary, fixing problems with the ADP systems after normal working hours.

The existing law states "no money appropriated by any Act shall be expended for telephone service installed in any private residence or private apartment for tolls or other charges for telephone service from private residences or private apartments, except for long-distance telephone tolls required strictly for the public business." The current state-of-the-art in computer science and telecommunications allows computer specialists to query, program, monitor, fix, start and stop computer programs and facilities while located at a remote site using a computer terminal over a telephone line.

Selected staff of the Division of Computer Research and Technology of NIH are responsible for insuring that certain programs such as the NIH Material Management System, and Central Accounting System, monitor the system after hours and is in addition to the staffs' normal daily work assignments.

In the event of problems or potential systems failure, they must access the system and determine and correct the problem. In some cases, this can be easily accomplished from a terminal at home, thereby significantly reducing computer down time, particularly where the employee lives a considerable distance from the ADP installation.

Section 215. None of the funds appropriated by this title are available for grants to the Federated States of Micronesia and the Marshall Islands: Provided, That funds made available to Guam, American Samoa, the Virgin Islands, the Northern Mariana Islands, and the Republic of Palau shall be available only in amounts that such entities would have received had the Compact of Free Association not been enacted. (Department of Health and Human Services Appropriation Act, 1986.)

Explanation

A Compact of "Free Association" had previously been negotiated with two of the three jurisdictions that make up the Trust Territory (the Republic of the Marshall Islands and the Federated States of Micronesia). The Compact established basic principles of relations with the U.S. Since approved by Congress, eligibility for financial assistance under most Federal programs, and all HHS programs, has now ceased. The change was made as insurance that those entities not covered by the Compact will not receive amounts greater than they would have received had the Compact not been enacted.

Title V

Section [514] 515. Upon the enactment of the Compact of Free Association for Palau, amounts appropriated by this Act for Federal financial assistance to [the Trust Territory of the Pacific Islands shall be available only for the Republic of] Palau shall not be available [but only in amounts that such Republic would have received had the Compact not been enacted].

Explanation

The Republic of Palau has not approved the Compact of Free Association and, therefore, HHS program funding for Palau will remain available in FY 1987 at levels previously provided to this territory. As was the case last year with the Marshall Islands and Micronesia, this provision will preclude a "double funding" windfall to Palau if and when the Compact of Free Association is approved for Palau and central funding established within the Department of Interior. Until enactment of the Compact for Palau, HHS financial responsibility to Palau is limited to its proportionate share of past years appropriations.

PROPOSED APPROPRIATION LANGUAGE

Mr. Natcher. We have just received from the President a proposed change in the language of Section 202 of the 1986 appropriations act, having to do with the number of NIH research grants. Please explain the effect of this language and tell us why you think it is necessary.

Dr. Bowen. The proposed new language would allow the Secretary of Health and Human Services, in light of appropriations available for FY 1986, to determine the maximum number of competing grants to receive support by the NIH. This language would replace previous appropriation language which specified that NIH support no fewer than 6,100 competing research project grants in FY 1986 and would allow for funding fewer grants under the sequestration.

This provision is intended to provide the NIH sufficient flexibility to award individual research project grants at levels more consistent with peer review recommendations and sound management practice. The new language will enable NIH to negotiate each award individually to maximize research progress, and reaffirms the importance of providing stability to the science base.

RESEARCH PROJECT GRANTS

Mr. Natcher. How many new and competing research grants would be supported: (a) If Congress approved your proposed 1986 rescissions for NIH; and (b) If Congress does not approve the rescissions?

Dr. Bowen. If the proposed 1986 rescissions for NIH are approved, 5,500 new and competing research project grants would be supported at the revised estimate, compared to 6,100 that would be supported if the rescission is not approved.

General Provisions

Mr. Natcher: We will insert the proposed language change in the record at this point.

Secretary Bowen: The language change follows:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

General Provisions

Section 202 of the General Provisions of the Department of Labor, Health and Human Services, and Education and related agencies Appropriations Act of 1986 (Public Law 99-178) is amended by striking out "no fewer than 6,100 new and competing projects" and inserting in lieu thereof "the maximum number of new and competing projects as the Secretary of Health and Human Services determines, in light of appropriations available for fiscal year 1986, would maximize scientific progress and enhance stabilization of the science base".

This language would restore the managerial flexibility necessary to insure optimal allocation of appropriations for the National Institutes of Health. This proposal would not affect outlays.

System to Monitor Social Security's Service to the Public

Mr. Natcher: As you know, this Committee has required that you design and put in place a formal system to monitor Social Security's service to the public. How will this system work?

Secretary Bowen: For many years, SSA has had measurement systems in place to monitor timeliness and accuracy of the work we do. These systems are prime indicators of the services we provide to the public.

We have submitted to the Committee the first quarterly report on levels of service to the public. That report contains data covering the December 1985 quarter compared to the last two years. It incorporates timeliness and accuracy data from the existing SSA quality control programs and the formats which will be used in future reports on average waiting times and commuting times. In January 1986, SSA field offices began collecting data on waiting time in SSA offices for the purposes of this report. This data will be included in the March 1986 quarterly report and all subsequent reports. SSA regions will also collect data on commuting time before and after changes in fields facilities. These data will be included as appropriate in future reports as facility changes occur.

I would also note that in January 1986, GAO released the report "Quality of Services Generally Rated High by Clients Sampled." Overall, four out of five persons rated SSA's services better than the service they receive from other Government agencies. According to the GAO report, "Most OASDI and SSI clients who visited SSA field offices waited no longer than they had expected for service and had enough privacy to conduct their business. Those who visited or reached SSA by telephone found SSA employees very courteous and clear in explaining the programs and rules, generally were satisfied to very satisfied with the amount of time it took to complete their business, and believed that SSA did a good to very good job in handling the purpose of the contact."

Upgrade of Computer Operations - SSA

Mr. Natcher: Over the last several years, Congress has approved your plans to invest more than $450 million to upgrade the computer operations at SSA. What is your view of the status of this project? Is it on schedule and within the budget?

Secretary Bowen: The Systems Modernization Plan (SMP) is now entering its final, or state-of-the art, phase after successfully completing the initial survival phase and laying the groundwork for future modernization in the transition phase. The plan's focus has shifted from solving immediate problems to one that stresses strategic planning. Although there have been revisions in some areas compared to the original 1982 plan, overall we have made significant progress towards a modern data processing and telecommunications system.

SSA Staffing Reductions

Mr. Natcher: Mr. Secretary, this Committee has been heavily involved in the issue of Social Security staffing reductions and office closings. Last year there were reports that your Department planned to close more than 200 offices and reduce staffing by more than 17,000 full-time equivalents. In response this Committee added $30 million to partially restore staffing cuts. While these funds were more than eliminated by Gramm-Rudman, we are still very much concerned about these issues. What are your current plans for Social Security staffing and offices?

Secretary Bowen: Our long-term plans for full-time equivalent (FTE) levels at the Social Security Administration (SSA) are consistent with the President's overall goal, stated in his Fiscal Year 1987 Management Message, of achieving a 20 percent increase in employee productivity in selected Federal programs. We continue to believe that we can reduce SSA employment within the six-year period, fiscal year 1985 to fiscal year 1990, to achieve approximately a 20 percent reduction in FTE's from the fiscal year 1984 level of about 80,000. We will approach this one year at a time as concrete management, procedural, and systems improvements permit us to maintain or improve our service levels while at the same time allowing us to decrease employment.

We have no current plans, nor have we ever planned, large-scale office closings. There is no reason to expect that office openings or closings this year or over the next several years will exceed the historical levels experienced in the past two years.

Reductions in SSA

Mr. Natcher: The President's budget proposes to defer an additional $30 million of Social Security funds on top of the Gramm-Rudman-Hollings sequestration of $144 million. Why is this deferral necessary and what are the eventual plans for these funds?

Secretary Bowen: In December 1985, evaluation of SSA's fiscal year 1986 resources requirements revealed that $30 million of the total obligational authority available to SSA for the Limitation (LAE) account in P.L. 99-178 was not needed at that time. There was every indication that public service was improving. Since SSA did not need the $30 million which Congress added in fiscal year 1986, SSA requested deferral of these funds.

The $30 million, which was previously deferred, has been superseded by the sequester required by the Balanced Budget and Emergency Deficit Control Act of 1985 -- i.e., they are not additive.

During the next few years SSA expects to realize savings from significant accomplishments in software modernization, including the nationwide implementation of the modernized claims systems. The new system will provide instant determinations of eligibility and entitlement, enhanced automated computations, and expanded automated control and audit functions. Modernization in this area will yield the greatest benefit to SSA in terms of operations and service to the public. Along with the modernized claims system, we will be implementing the nationwide Data Communications Utility network, developing a data base architecture and installing new hardware and software in the program service centers.

There has been some slippage in the schedules implementation of the claims modernization process, and we took this into account in developing the fiscal year 1987 budget request. SSA will continue to make appropriate adjustments from year-to-year; however, SSA is still convinced that the long-term estimates are in the ballpark. Experience in our York, Pennsylvania and Baltimore, Maryland pilot offices confirms this. Obviously, a plan of this magnitude involves scheduling changes which affect the timing of obligations and anticipated savings.

The original SMP released in March 1982 included a five-year estimate of the plans cost. The current 1986 SMP update released in November 1985 reestimated these costs for the first five years and the comparison is as follows:

(In millions of dollars)

	March 1982 Estimate	Current Estimate	Change
Five-year SMP costs (Mar 1982 - Feb 1987)..	$479	$493	+$14

The net difference between the original plan and the current estimate for the five-year period is $14 million.

Social Security Administration

Mr. Natcher: Last year one of your principal contractors was suspended for making fraudulent presentations to SSA. In addition, there has been a great deal of turnover of the key staff on this project for a variety of reasons. How serious are these problems?

Secretary Bowen: In March 1981, SSA entered into a contract with the Paradyne Corporation to provide terminal equipment for SSA offices nationwide. The equipment acquired under the contract is now performing satisfactorily. Paradyne was indicted by a Florida grand jury on December 12, 1985. The indictment charges that Paradyne mislead SSA during the proposal evaluation phase of the acquisition by a fraudulent demonstration of the equipment. On the basis of the indictment, Paradyne was suspended on December 16, 1985 from doing business with the

Federal Government. The terms of the suspension allow the ongoing contract to be renewed if it is determined to be in the Government's best interest. SSA plans to renew the Paradyne contract until a competitive replacement of the equipment is completed.

The original 1982 Systems Modernization Plan stated that "the loss of experienced programming and systems analysis personnel and the inability to recruit and replace competent ADP personnel compounds the Agency's systems problems." Since that time there have been significant improvements both in reducing turnover of key staff and in recruiting competent personnel in SSA.

Over the past year, only one key person at the GM-15 level left SSA's Office of Systems. During that same period, three people were recruited from outside the Social Security Administration at the Senior Executive Service level together with eight people at the GM-15 level. These 11 senior level systems professionals, with backgrounds in diverse specialty areas, were obtained through an aggressive advertising and recruiting campaign. Coupled with this was a successful effort to locate and develop new entry-level recruits. As a result, in fiscal year 1985, 130 computer programmers were hired, many of them new college graduates. In addition, 25 college students were recruited to work as summer interns.

Reduction in SSA Employment

Mr. Conte: Now I see that the budget proposed to reduce SSA employment by another 2,000 positions. Is this part of the six-year plan to reduce employment by 17,000? (If not, then on what basis do you propose to cut another 2,000 positions?)

Secretary Bowen: The six-year plan to reduce 17,000 full-time equivalents (FTE's) is an overall target consistent with the President's overall goal of achieving a 20 percent increase in employee productivity in selected Federal programs. We will continue to approach this one year at a time as concrete management, procedural, and systems improvements permit us to maintain or improve service levels while at the same time allowing SSA to decrease employment. In fiscal year 1985, FTE's for SSA's Limitation account were reduced by about 2,200 from the fiscal year 1984 level. For fiscal years 1986 and 1987, SSA has identified additional improvements which are expected to save 72 FTE's in fiscal year 1986 and an additional 2,899 FTE's in fiscal year 1987.

FAMILY PLANNING

Mr. Conte. Assuming no block grant is passed, are you planning any changes or proposals with regard to either the Title X regulations or the Title X guidelines?

Secretary Bowen. The current regulations date from 1980 and the guidelines from 1981. Both of these have been looked at over the years for possible changes and updates but at this time there are no specific regulations or guideline changes in the development or clearance processes.

I can not rule out at this point the possibility that we might propose some changes sometime during the next year.

TEENAGE PREGNANCY

Mr. Conte. Given all the recent concern over teenage pregnancy, and the need for more concern and involvement in this area, it would seem that, rather than trying to whittle away at the Title X program, policy efforts should be directed at increasing the number and range of programs capable of addressing the adolescent pregnancy issue. Would you agree, and is the Department planning any response to the raft of recent reports on this area of great concern?

Secretary Bowen. Recent interest in teen pregnancy has been significant in that it has focused on causes and factors too long ignored: the importance of the family, the importance of values, and the importance of young people understanding the consequences of their actions and taking responsibility for their actions.

I am very interested in this issue and I have initiated discussions within the Department about what action the Department should take to contribute to the solution of this problem. I want to emphasize, however, the government's role in this area is necessarily and properly secondary to the roles of families, churches, synagogues and communities. We can provide funds and services and support research, but the actual work of teaching children about sex, love and values is something that has to happen at home.

With regard to the government's role, we have not reduced the Title X Family Planning program, nor the Adolescent Family Life program. We have proposed that administration of the Family Planning program be shifted to the States through a comprehensive Primary Care Block Grant, because we feel that that will allow this program to be better coordinated with the other programs which target on this problem, including the Maternal and Child Health and the Social Services Block Grants.

OFFICE OF MINORITY HEALTH

Mr. Conte. The department issued an eight volume report last year in one of only the most recent studies to point out the growing health gap between whites and blacks in this country. What current programs does the department need to target to improve the health status of blacks and minorities, and how do you plan to achieve some success in this area without proposing any substantial budget increases?

Secretary Bowen. Of the variety of health care programs conducted by DHHS, some are directed at the poor and minority populations, while some are of a general nature benefitting all Americans. The Office of Minority Health will seek to redirect current DHHS resources in ways that will more efficiently target the health problems that generate the disparities between blacks and whites.

For example, the Task Force Report on Black and Minority Health highlights the importance of health information and health behavior in contributing to these health disparities. Major advances can be made by improving the awareness and decreasing behavioral risk factors. Similarly, current research efforts can be redirected to more accurately target the health problems of minorities which we don't fully understand.

Mr. Conte. What will be the role of the new Office of Minority Health in overseeing the department's efforts? Does the director of that office report directly to you?

Secretary Bowen.

- The Director of the Office of Minority Health reports directly to the Assistant Secretary for Health and serves as his principal advisor for health program activities that address black and minority populations; he also serves as chairman of the Minority Health Coordinate Committee composed of relevant staff of PHS and HHS.

- The Office, working closely with PHS agencies and other DHHS components in a coordinative and advocacy role:

  (1) Establishes near-term and long-range objectives for DHHS health activities addressing minority populations;

  (2) develops reporting and monitoring requirements for those objectives;

  (3) organizes and plans specific activities to meet minority health needs and monitors the DHHS budget to assure an appropriate share of funds is devoted to minority health problems;

  (4) provides ongoing technical assistance to States and works closely with public and private sectors to assure minority health issues are addressed;

  (5) serves as a resource in the promotion, investigation, development and implementation of innovative health care models culturally unique to minority populations;

  (6) conducts, reviews, and develops strategies to improve the availability and accessibility of health professionals to minority communities;

  (7) conducts, sponsors, and facilitates conferences on minority health;

  (8) assures that steps are taken to improve data sources and integrate data system reflecting minority populations; and

  (9) facilitates research in and fosters public awareness of research in factors affecting minority health.

President's Welfare Study

Mr. Conte: Mr. Secretary, in his recent State of the Union message the President called for a one-year review of the nation's welfare system. He reiterated that message when he spoke at your Department the next day, I believe. Since then we've seen a few articles in the papers but nothing really substantial. Can you give us a good idea of the scope and aim of this study, and which programs will be under review?

Obviously, as Secretary of HHS, you command the greatest number of our welfare programs and would seem the likely choice for heading up the team conducting this study. That's not the case. Why is is that someone from outside the Department was chosen to chair this review?

Secretary Bowen: Because programs designed to help the poor are administered by several government agencies -- HHS, HUD, USDA, DoL, Department of Education, etc. -- a wide ranging view of poverty and family dependency is needed. The President has decided that such a multi-dimensional perspective can come only from a review carried out at the highest level, and has asked the Domestic Policy Council (DPC) on which I serve, to oversee the study. We are active participants on the DPC working group and expect to be involved in the deliberations leading up to and including the recommendations to be presented to the President in December.

Boston College

Mr. Conte: Mr. Secretary, in last year's Bill we included $500,000 in the Office of Planning and Evaluation to continue a project on the Multi-Regional Policy Impact Simulation Model. That project has been on-going for five years at my Alma Mater, Boston College. Recently the College contacted me to say that, under some strange application of Gramm-Rudman, the project was going to be cut in half, and the remainder eliminated through rescission. First of all, since the $500,000 for this project was clearly outlined in our report, shouldn't the Gramm-Rudman bite be only about $21,000 or 4.3 percent?

Can you tell me if the Department is also proposing to rescind funds for the project on top of the Gramm-Rudman reduction?

Secretary Bowen: The information Boston College has on funding the Multi-Regional Policy Impact Simulation (MRPIS) Model is inaccurate. First, under sequestering procedures, funding for that project--since it is a "program, project, or activity" as defined by the Emergency Deficit Reduction Act--will be reduced by 4.3 percent or $21,500.

Second, under the proposed rescission of $220,000 for all the Policy Research account--which would bring funding of that account to $6 million, the amount originally proposed by the President for fiscal year 1986--the entire cut would come from the MRPIS project.

Third, given the very limited utility of MRPIS to this Department, we may submit a reprogramming request to shift the remaining fund from MRPIS to other Policy Research projects of higher priority to HHS.

MRPIS is of little utility to this Department. It measures broad economic impact of major Government policies and programs (such as tax policies). It does not provide us with the kind of information we need on those sectors of the economy or population of direct interest to us--health care and financing, social services, the aging, the poor, etc. For these, we have our own models which are specifically designed to handle our analytic needs.

MASSACHUSETTS HOSPITAL OVERPAYMENT PROBLEM

Mr. Conte. Hospitals in Massachusetts were recently told that they would have to repay the Health Care Financing Administration (HCFA) around $60 million this year. The hospitals were told that they were overpaid over the past three years when they were "waivered" from the normal Medicare Reimbursement rules.

The hospitals tell me, however, that the information HCFA is using to collect the overpayment is not finalized. The hospitals do not argue that they may not owe any money -- they just want to wait until final data is available. What is the status on the overpayment? Do you think the data is finalized?

Secretary Bowen. When the demonstration originally was approved, the terms and conditions attached to the Medicare waiver award letter established a statewide maximum liability cap at 1.5 percent below the average rate of increase in nationwide Medicare expenditures. Subsequent Federal legislation relaxed the cap level to the average rate of increase in nationwide Medicare expenditures.

The waiver terms and conditions also specified that "Medicare will reduce its interim payments to hospitals in any quarter in which, based upon the data available for computing the "cap" (including actuarial projections of the previous year's average Medicare nationwide rate increase), it becomes likely in the judgement of the Medicare program that the "cap" will be exceeded over the 3-year period." Although we had considerable discretion in interpreting this condition, we chose an implementation plan which is advantageous to Massachusetts hospitals and which provides reasonable time frames for financial planning and cash flow management. The cap plan which we agreed upon calls for an annual calculation of the cap beginning with the Winter of 1984-1985, and a quarterly cap recoupment process in the event the cap is exceeded.

According to the cap plan, cap recoupment relative to the first demonstration year was to have begun in April 1985. In deference to the Massachusetts Hospital Association's arguments that the data were less complete than anticipated and that the following years would reverse the first year cap overpayment, we temporarily postponed recoupment. Unfortunately, the inclusion of Medicare liability data from the waiver cost reports filed by the hospitals for the second demonstration year increased the cap overpayment and makes it appear very unlikely that the cap payment will be eliminated as the expenditure data become finalized. As such, we felt that our decision had to be to initiate the quarterly cap recoupment process for the $15,772,520 first year cap overpayment beginning in January 1986. The first quarter's total statewide cap recoupment amount was $3,943,130, as compared to the current calculations of the liability for the first and second demonstration years, which show the total overpayment to be approximately $52 million.

The quarterly cap payments which are being requested of the hospitals in April 1986, July 1986, October 1986 and January 1987 will reflect the $52 million cap overpayment which resulted from the recently completed second annual cap calculation. This overpayment amount includes both the first and second year of the demonstration and has been revised to reflect the updated nationwide rates of increase and Massachusetts expenditure data.

Annual cap calculations are planned for the next four years. Each year the expenditure data will be updated as hospitals' settlements become increasingly finalized. In the later years, only very small adjustments would be expected as remaining audits and appeals are closed out.

Mr. Conte. I coordinated a letter, signed by the Massachusetts Delegation, to Mr. Haddow at HCFA, asking him to hold off on this collection for the time being. Is there any chance that could happen? Would you be willing to let them pay back any overpayment after you have final numbers agreeable to all parties?

Secretary Bowen. There is no technically valid justification for further postponement of the cap overpayment. Recoupment of the cap overpayment for the first demonstration year was postponed for 9 months until it became absolutely clear that the cap would be exceeded over the 3 years of the demonstration.

The cap recoupment process is now being implemented according to the cap plan which was submitted by the Massachusetts Hospital Association (MHA) and approved by HCFA. It was well understood and accepted by all involved parties that the annual cap calculations would not be based on finalized liability data. The MHA negotiated strongly for interim cap calculations because they felt that there would be savings generated from the project which would be returned to the .hospitals. As a result, annual cap calculations are planned and cap revisions will become increasingly small as the liability data is finalized.

In addition, we feel that the final data will show the hospitals to be over the cap for the 3-year demonstration period, and will not change the fact that the hospitals are in an overpayment situation. Even the MHA has not argued that in the final tally there will not be a cap overpayment. We feel that we should adhere to the cap plan and begin reducing the cap overpayment at this time.

Mr. Conte. There were three other States that were waivered for some time over the past three years - Maryland, New Jersey and New York. Are any of those States being asked to repay any money?

Secretary Bowen. Maryland and New Jersey were under demonstration waivers during 1977-1985 and 1982-1984, respectively; and both projects ended with the States under their caps.

The cap for Maryland and New Jersey was designed in the late 1970s and was our best attempt to protect the Medicare trust funds. In later years, based upon our experience with the above preliminary projects, we designed a different cap for New York and Massachusetts.

New York which was a waivered State during 1983-1985, has a similar cap to Massachusetts. Results from the first two years of the demonstration indicate that New York is under its' cap.

Mr. Conte. Do you think that if the State of Massachusetts had implemented a different reimbursement system, such as the one used by Maryland, they would have to pay back any money?

Secretary Bowen. Regardless of the specific reimbursement system chosen by the State of Massachusetts, there still would have existed the potential for exceeding the cap. We have found that the more effective programs are those that require participation and compliance by all hospitals, limit or preclude negotiations with hospitals, disallow a portion of the cost of high-cost hospitals, and provide incentives for reductions in length of stay. In that context, it is important to note that even though participation in the demonstration was mandated by State law, the Massachusetts program is based on a negotiated contract between Blue Cross and the hospitals. As structured, the system protected the status quo for all hospitals and only demanded equal productivity improvements from each.

At this time, it does not appear that the actual payment patterns resulting from the contract were any different than expected at the total hospital payment level. The reason the hospitals are having difficulties in staying within the cap seems to be the fact that the State system isolated the hospitals from national trends in Medicare's health care costs and utilization.

Medicare costs were substantially controlled nationwide as a result of the effectiveness of Medicare's total cost-per-case limits in 1983, the new prospective payment system in 1984, and the significant change in Medicare admission patterns. It appears that the Massachusetts system could not match the effectiveness of Medicare's nationwide system. Whether another State system would have had better results in Massachusetts is impossible to predict because the administration of the system would certainly have been different.

Mr. Conte. Do you think that the Massachusetts waiver saved the Medicare system any money, comparing the hospital reimbursement in the State with what they would have been paid under the prospective payment system (PPS)?

Secretary Bowen. During the first year of the demonstration, FY 1983, the nationwide Medicare payment system was based on the payment system enacted in the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). For the second and third demonstration years (FY 1984 and FY 1985), Medicare's PPS was the national system.

There are technical difficulties in comparing the demonstration payments to what might have been paid to Massachusetts hospitals under TEFRA and PPS. The main problem is that we can not know exactly how the hospitals would have responded under a different set of payment incentives, especially in relation to changes in admissions and case mix.

Our demonstration payment data, compared to our current estimations of what might have been paid under TEFRA and PPS for FY 1983 and FY 1984, show that the Massachusetts hospitals would have been paid less under TEFRA and PPS than they have been paid under the waiver. It appears this trend would continue for a waiver versus PPS comparison for FY 1985.

HOSPITAL CAPITAL

Mr. Conte. What is happening with including capital costs for hospitals in the diagnosis related group (DRG) calculation formula? When will they start to be used?

Secretary Bowen. The President's 1987 budget submission to the Congress provides for incorporating capital-related costs, which are now paid for on a cost reimbursement basis, into the standardized amounts used to pay for hospital inpatient operating costs under the prospective payment system (PPS). The incorporation of capital would begin with hospital cost reporting periods beginning October 1, 1986 and onward. The specific provisions for folding capital into PPS will be contained in the Department of Health and Human Services' report on incorporating capital (required by P.L. 98-21) which will be submitted shortly. The specific recommendations are expected to provide for including a reasonable amount for capital costs in the standardized portion of the PPS payment in steps over a transition period, during which time hospitals will receive the lesser of a proportion of their actual costs limited by their amount in a base year (1986) trended forward.

SAVINGS UNDER PROSPECTIVE PAYMENT SYSTEM

Mr. Conte. Does the Department have any firm numbers on how much the Government has saved under the Prospective Payment System? How about in two more years, when it is fully phased in -- will we be saving more?

Secretary Bowen. The establishment of a prospective payment reimbursement system (PPS) was enacted as part of the 1983 Social Security Amendments of 1983. Since this legislation followed closely behind the changes to the hospital reimbursement system enacted in the Tax Equity and Fiscal Responsibility Act (TEFRA), it was budget neutral for the first two years, 1984 and 1985.

SUPPLEMENTAL SECURITY INCOME DEEMING WAIVERS

Mr. Conte. I'm very interested in the so-called "Katie Beckett" waivers that the Department was issuing in 1983 and 1984. As you know, these waivers waived the normal income deeming requirements for SSI, so that families with abnormally high medical expenses could become entitled to Medicaid even if their income placed them over the SSI guidelines, and if they could be cared for more cheaply at home.

At the end of 1984, the Department stopped issuing waivers, with the expectation that the States would set up their own waiver programs. My own State of Massachusetts applied for a waiver late last year.

Could you check on the status of the Massachusetts waiver request? Does it look good? How long will it be before a decision is reached?

Secretary Bowen. On October 4, 1985 the Health Care Financing Administration (HCFA) received a request from the State of Massachusetts for a home and community-based services waiver for disabled children, authorized under section 1915(c) of the Social Security Act. As part of its request, the State indicated its intention to treat individuals under the waiver as if they were institutionalized for the purpose of applying the Medicaid deeming of income requirements.

The waiver request was reviewed by the HCFA staff and found not to conform fully to the statutory and regulatory requirements. As authorized by section 1915(f) of the Social Security Act, a formal request for additional information was forwarded to the State by the Boston HCFA Regional Office on December 30, 1985. The State has not yet responded to that request. However, as soon as a response is received, HCFA will act expeditiously to complete its review of the waiver.

Mr. Conte. To the best of my knowledge, two of my constituents applied for an SSI income deeming waiver. One was granted, and one is pending, but it seems to take an extraordinarily long amount of time before any decision is made.

What caused and is causing the hold-ups? How many undecided cases does the Department have pending? Can you give me some assurances that decisions will be made soon?

Secretary Bowen. On May 6, 1982, then Secretary Richard S. Schweiker established the Intradepartmental Board for SSI Deeming Determinations. The Board was delegated authority, pursuant to section 1614(f) of the Social Security Act, to determine the extent to which it is inequitable under the circumstances to deem the income and resources of an applicant for supplemental security income to include the income and resources of family members. The Board's authority was extended until December 31, 1984, and was authorized to dispose of any requests submitted to the Department by December 31, 1984.

Since the Board was established, it has received about 300 requests from the States, of which about 200 have been approved. There are now about 50 pending cases which have not been decided, some of which were submitted by the States just prior to December, 1984. The rest were withdrawn. In reviewing the requests the Board has attempted to exhaust all possibilities of entitling the individuals to benefits. As a result, some cases have required extensive development and additional information, which takes additional time.

In order to expedite the review process, on February 28, 1986, HCFA was delegated the authority to decide the remaining pending requests. All decisions are expected to be made within 90 days.

Mr. Conte. I also have a constituent whose daughter would have clearly qualified for a waiver, but no application was made until last year. Now, she has to wait until the Massachusetts waiver request program is approved.

Do you see any need for Federal legislation on this issue? Would the Administration support legislation establishing a comprehensive, less complicated SSI income deeming waiver program at the Federal level? Are the State programs now in effect working?

Secretary Bowen. We do not see the need for any additional Federal legislation to deal with this issue. The Intradepartmental Board was intended as an interim solution to deal with individual eligibility problems. A number of other options are now available for States to help these people and reduce the cost burden on Government programs. Under the Tax Equity and Fiscal Responsibility Act of 1982 a State has the option of amending its State plan and covering under Medicaid certain disabled children age 18 or under who are living at home. A State can extend such protection to an individual who would be eligible for SSI, and therefore Medicaid, if he or she was in a medical institution. This provision became effective on October 1, 1982, and must be made available on a statewide basis. A State may also request a home and community-based services waiver under section 1915(c) of the Social Security Act.

Section 1915(c) authorizes the States, under a Secretarial waiver, to offer a wide array of home and community-based services, including any cost-effective services not covered under the State's regular Medicaid program, that an individual may need to avoid institutionalization. Under a section 1915(c) waiver, States may furnish approved home and community-based services to individuals who would be Medicaid-eligible if institutionalized, even if they would be ineligible for Medicaid while living at home because of the SSI deeming rules, or some other reason. States can thus prevent unnecessary institutionalization by providing medical services at home and in the community.

To date, there has been a great deal of interest by the States in the home and community-based services waiver program. As of March 10, 1986, we have approved 123 requests from 46 States, including 22 "model" waivers (limited to 50 persons) from 15 States. At the present time, there are 91 active approved waivers from 42 States, including 20 model waivers from 15 States. Forty-nine of the active approved waivers have waived the normal SSI income deeming rules in determining eligibility.

Mr. Conte. Did the Government save money in terms of decreased Medicaid expenses during the waiver period? Have the States saved money? Can you tell the Subcommittee how much?

Secretary Bowen. One of the requirements that the Intradepartmental Board has used in determining whether to grant a waiver of the normal SSI income deeming rules is whether the person could be treated at home at a lower cost to the Government than if he or she were institutionalized. Thus, in each of the approved waivers, it was shown that there would be decreased Medicaid expenses. Since each of these cases was then merged with all other Medicaid-eligible cases in the State, we do not have any data as to the costs of their care.

Catastrophic Illness Study

Mr. Roybal: Dr. Bowen, both you and the President have made commitments to come up with a plan to protect all Americans "...whose life savings would otherwise be threatened when catastrophic illness strikes." How will the plan you are developing help the victims and families who are underinsured against the personal and financial burden of long-term and catastrophic illnesses such as Alzheimer's disease?

Secretary Bowen: One of the three major components of the Department's study will address private financing of long-term care. Providing long-term care for the Nation's frail elderly is an important public concern. The growing demand for long-term care services comes at a time when the public sector is facing increasing fiscal constraints, thus increasing the role of the private sector.

In considering long term options for private financing of long-term care, the Department's study will review intermediate steps that States, the insurance industry, and providers can take to advance in the spirit of private-public collaboration.

Mr. Roybal: How will your plan provide catastrophic and basic health insurance protection for the 30 to 40 million uninsured Americans of all ages?

Secretary Bowen: The Department must first study the issue of catastrophic illness to thoroughly address the scope of the problem. For example, the Public Health Service has data from the National Medical Care Expenditure Survey (NMCES) which contains important information on the health insurance status of Americans revealing which population subgroups are most likely to experience medical expenses beyond their ability to pay. Although most Americans have health insurance, more than half of the population under 65 have no limits on their out-of-pocket expenditures for medical care.

A major focus of the Department's study is to evaluate programs designed to provide protection from catastrophic medical expenses for those with less than adequate private insurance coverage. About nine States have some form of catastrophic illness protection. Such State experience has been mixed and should be evaluated.

AIDS SERVICE DELIVERY DEMONSTRATIONS

Mr. Roybal. Your budget proposes to rescind $15 million for AIDS demonstration requests. Is this a request which was initiated by you or was it part of the budgetary advice received from OMB?

Secretary Bowen. The rescission proposal reflects the agreement between the Department and OMB on ways to more precisely control the level of overall expenditures. As a Department, we did not initially recommend a rescission of these funds.

Mr. Roybal. Without the funds for these demonstrations, how does the Department plan to deal with the need to develop less costly care and treatment at the community level for AIDS victims?

Secretary Bowen. The Department has been encouraging cities with high inpatient care costs for AIDS to adopt elements of the San Francisco Health Commission model which emphasizes increased use of less costly outpatient services. In addition, the Robert Wood Johnson Foundation has recently announced a private initiative to award $17.2 million for demonstrations in less costly health care delivery models for AIDS patients. The Foundation has stated that it expects to award grants to 10 cities from a list of 21 metropolitan areas with high AIDS costs.

Mr. Roybal. What research is being done by the Department in the area of lowering the costs of care and treatment?

Secretary Bowen. Through the Health Care Financing Administration (HCFA) and the National Center for Health Services Research (NCHSR), the Department spends a large amount of money (approximately $36 million together requested for 1987) on general research in health services and health care cost containment, including research on alternatives to more expensive inpatient care, such as hospices, home health, and adult out-patient services, which have applications to AIDS care and treatment costs. In addition, the Department's continues to support epidemiological studies, research on therapeutic treatments and vaccines, and preventive educational programs for AIDS. If these efforts are successful, they could significantly affect the cost of AIDS care.

MEDICARE PHYSICIAN PAY FREEZE

Mr. Hoyer. Dr. Bowen, as I understand it the Administration has proposed continuing the physician pay freeze under the Medicare program.

H.R. 3128, the Budget Reconciliation Bill, on the other hand has a House provision which provides for a 1 percent increase in physician payments. I also understand that the Administration may attempt to continue the freeze through Administrative actions.

What is the current Department and Administration proposal on this issue?

Secretary Bowen. When discussing the merits of extending the freeze, it is important to keep in mind what has happened to budget outlays for physicians' services since this Administration has been in office. During the period of FY 1981 to FY 1985, a period that included the orginal 15-month fee freeze, budget outlays for physicians' services grew at an average annual compounded rate of 15 percent. This is greater than the rate of increase for the budget as a whole or even for national defense. During FY 1985, under the freeze, the rate of increase in spending for physicians' services continued to outpace the increase in the physician services component of the CPI.

The President's FY 1986 budget proposed a continuation of the fee freeze for another year. Congress has extended the freeze through March 14th. We see no reason to change our position and would therefore support an extension of the freeze through the remainder of this fiscal year.

In regard to FY 1987, there is no plan to continue the freeze through administrative action. Customary and prevailing charges will be updated on October 1, 1986. In determining the level of prevailing fees determined by the Medicare economic index, we will be taking action to correct an overstatement in one component of the index. This action is required in order to use the best available data in determining the index as the Secretary must do according to statute. However, even after taking into account this adjustment and the effect of all the other FY 1987 proposals, budget outlays for physician services will increase. If viewed in the context of the total Federal budget, this would be the second largest increase, larger than the proposed increase for national defense and interest on the debt.

BUDGET INCREASES IN OTHER AGENCIES

Mr. Hoyer. The Administration's budget provides for research and development increases for NASA, DOD, NSF, etc. of approximately 16 percent. At the same time outlays at NIH are being cut. It appears that what's good for the gooses is not good for the gander. Why is that?

Dr. Bowen. Policies are set by the Administration that have given a high priority to those areas of research that contribute to the national defense. Although the NIH is being reduced in FY 1987, the agency will still be able to maintain a strong and viable research program.

NATIONAL CENTER FOR NURSING RESEARCH

Mr. Hoyer. NIH staff are moving ahead to develop a Legislative Implementation Plan for the new National Center for Nursing Research. If 1986 funding for the Center is to be rescinded and elimination of funding is to be effected in 1987, what are the Administration's plans, including timetables, to establish the new Center?

Dr. Bowen. The timetable for establishing the new Center is dependent upon the resolution of the President's rescission package pending before Congress. The NIH would expect to initiate a Search and Screen Committee to identify an NCNR Director as soon as the request to establish the position is approved.

NURSING RESEARCH

Mr. Hoyer. According to recent data collected by the American Association of Colleges of Nursing, enrollments in generic baccalaureate nursing programs have declined 7.6 percent between Fall, 1984 and Fall, 1985. Nursing shortages are once again being felt and are predicted to become more problematic due to decreasing enrollments.

Federal support is critical to the survival of many nursing programs, and the President's budget proposes rescission of most of the Division of Nursing 1986 funds and total elimination of these funds in 1987. Oversupply statistics pertinent to physicians do not apply to nursing.

Therefore, what rationale does the Administration have for rescission and then elimination of funds for nursing education and research?

Secretary Bowen. The most reliable information regarding trends in admissions and enrollments in schools of nursing is provided by the Annual Survey of the National League for Nursing covering all schools of nursing. The latest information is for the academic year 1983-84 in which admissions of generic students to baccalaureate programs increased by 5.7% over the previous year. Total enrollments are a less reliable indicator of trends because they are affected by numerous factors such as changes in length of program and attrition rates. Evidence presented in the Fifth Report to the Congress on the Status of Health Personnel in the U.S. found no aggregate imbalance between supply and requirements in the foreseeable future. Profound changes in the health care delivery system could alter the supply-demand equation, but there is no quantifiable evidence to date to document the impact of such changes.

Mr. Hoyer. What evidence does the Administration have indicating that other funding sources are available to replace Federal funding for nursing education and research?

Secretary Bowen. The past twenty years of federal support has substantially increased the capability of schools of nursing to add to the nurse supply. Baccalaureate programs are now firmly established in academic settings and have available to them the same resources as are used for other health disciplines.

Mr. Hoyer. In 1985 your predecessor, Mrs. Heckler, established a Center for Nursing Research in the Division of Nursing. However, no funds were made available by the Administration to establish the center. The Congress mandated the establishment of a National Center for Nursing Research at NIH in P.L. 99-158, and now the Administration proposes a total rescission of the $5 million appropriated by Congress to establish the new center--P.L. 99-88.

What is your rationale for proposing this rescission in light of a clear Congressional mandate to authorize and appropriate funds for the National Center for Nursing Research and in light of serious evidence of need for nursing research funds according to a 1985 Institute of Medicine Study?

Secretary Bowen. The rescission request is a part of the President's overall budget reform plan to curtail Federal Government spending. Taking into account the future projections of requirements and the available supply, and given the anticipated flow of graduates and current trends in the work patterns of the registered and licensed practical nurse population, the Administration continues to believe that no aggregate shortage exists, now or in the foreseeable future. Therefore, rescission of these funds is desirable.

USER LIAISON PROGRAM

Mr. Hoyer. Dr. Bowen, this question pertains to the role of this Department in providing information and assistance to State and local government in the health and human services arena.

I am pleased to notice that the Federal government has taken on an increasingly significant responsibility for providing timely and appropriate information and assistance to State and local governments through a variety of useful mechanisms - some of which are carried out by components of this Department.

For example, the National Institute of Mental Health was given legislative authority in 1984 to carry out a number of activities designed to provide state-of-the-art information and technical assistance to a variety of state and local health leaders. In fact, the Institute has recently announced that it will shortly fund a 3-year contract to develop and disseminate needed information to State legislators through a variety of techniques, including: workshops, seminars, and technical assistance.

Another of the Department's research organizations with similar legislative authority, the National Center for Health Services Research, has also been providing this type of assistance to state and local government officials the past 8 years: through what is called the User Liaison Program. I have had several communications from State legislators and executives in Maryland who have participated in this Program expressing just how valuable these activities have been. Other members of this Subcommittee have had similar communications from both legislative and executive branch officials in their states attesting to the value of this Program. More specifically, at the request of the Chairman of the Committee that handles health issues for the Maryland House of Delegates, the User Liaison Program conducted a workshop on health policy analysis and unfortunately, the funding for the User Liaison Program activities which these state officials have found so valuable has been eliminated by the Director of the National Center for Health Services Research. Specifically, the NCHSR Director has eliminated the contract funds for this fiscal year that would have supported workshops, seminars and technical assistance to the states and has not requested any funding for these types of activities in FY 1987.

Both programs are very important and serve a valuable purpose. Why, then is one being continued and the other being eliminated? If you can't answer now, I would appreciate a response prior to our hearing with the Office of the Assistant Secretary for Health on March 19.

Secretary Bowen. While NCHSR plans to eliminate most of the workshops and syntheses of research information for Fiscal Year 1986, the program has already expended $324,000 on these activities for this year. Analysis of spending of the funds allocated to the User Liaison Program shows that over 60 percent of the money is obligated for travel and subsistence of State officials attending these conferences, together with contractor overhead and fees.

The Director of the National Center has determined that more cost effective alternatives must be developed. We clearly agree that it is important to make the results of important health services research and policy analysis available to responsible individuals at the State level. Given resources available to the National Center, however, maintaining the program at levels which subsidize attendance of State officials at meetings would have an adverse effect on the funds available for research which is the primary mission of NCHSR.

NCHSR will continue not only to disseminate research results through its inhouse dissemination program, but it will establish within the User Liaison Program a research and technical assistance referral and coordination service. There are presently 35 health services research and policy analysis centers based in academic institutions or in State governments, in 28 states. NCHSR believes that it is more appropriate for State officials to work with such centers within their state or region, rather than relying on consultants being provided by Washington.

Even at the reduced level of support for the User Liaison program in 1987 of $175,000, out of a total obligational level for NCHSR research of $22.8 million, this activity is still a larger proportion of the total NCHSR budget than the proposed NIMH research dissemination contract of $100,000, which is out of a total NIMH research request of $195 million.

Mr. Hoyer. Mr. Secretary, I would now like to ask a broader question. Do you agree that it's crucially important to get Research findings in the hands of state executives and legislators? Will this policy have the support of your Administration? Would you agree that such a policy maximizes the benefits of this significant research?

Secretary Bowen. It is important to make these research findings available to State executives and legislators. It is equally important to provide technical assistance around specific issues. NCHSR has done both and will continue to do both. I would like to provide for the record two lists. One is a list of currently supported NCHSR research activities identified by categories which have been the focus of interest for many State legislators. Second, is a list of technical assistance provided by NCHSR's intramural program to a variety of users including, but not limited to, State and local officials. Our intent is to focus more of the activity on this kind of specific hands-on technical assistance rather than more generic meetings which are attended by only a small percentage of State legislators who might be interested.

Following is a list of NCHSR supported projects.

Access to Care

Impacts of Medicaid and BCHS Projects on Access to Care
Access to Services by the Urban Elderly

Ambulatory Care

Consistently High and Low Elderly Users of Medical Care
Ambulatory Care Visits Outside the Private Sector
Utilization of Ambulatory Health Services by Hispanics
Demand for Outpatient Health Care by Choice of Provider
Patients Use and Perceptions of Minor Emergency Centers

Emergency Medical Services

Instant CPR Instruction via Phone

Home Care

Cost and Efficacy of Home Care for COPD Patients
Evaluation of a Comprehensive Home Care Program for the Elderly

Legal Issues

Malpractice Claims: The Maryland Experience, 1977-1985

Nursing Home Issues

Predicting the Course of Nursing Home Patients
Outcomes of Nursing Home Discharges
Significant Savings Possible for Nursing Home Care

Planning and Regulation

Prevention and Public Programs: Pricing and Promotion
Evaluation Study of an Alternative Birthing Center
Analysis of the Utilization and Economic Impact of the State of Kentucky's Generic Drug Substitution Legislation
PPOs: Does Performance Equal Promise
Hospital Use Rates in Local Communities in Michigan
Resource Utilization Alternative Ambulatory Care Sites
Evaluating Preventive Medical Care as a Health Strategy
Small Area Variation in Hospitalized Case Mix
The Benefits and Costs of Anti-Smoking Policies

Quality of Care

Strategies to Reduce Inappropriate Use of Blood Products
A Utilization and Outcome Evaluation of Infant Transport
Appropriate and Inappropriate Use of Ancillary Services
Prevention of Nonelective Hospital Readmissions

Reimbursement

Profile of the Financial Burden of High-Cost Illness
A Study of Maine's Catastrophic Illness Program
An Analysis of Employer Innovations to Control Health
Health Care and Insurance Loss of Working AFDC Recipients

Operation and Performance of HMOs

Policy Implications of Hospital Market Structure

Technical Assistance Provided by Intramural Research Program
Fiscal Year 1985 - First Quarter FY 1986

Date	Group or Organization	Assistance Provided
1/85	Department of the Treasury	Provided estimates of employment-related coverage.
1/85	Health Care Financing Administration	Tables on medical equipment and supplies, purchases and rentals expenditures, and sources of payment.
1/85	Health Care Financing Administration	Estimates on persons 70 years of age and over covered by Medicare in 1977.
12/84	Congressional Budget Office	Analysis of how many visits with hearing aids.
11/84	GAO	Estimated percent of family income spent on medical care.
11/84	Department of the Treasury	Analysis of subscribers with family and individual plans and zero employer contributions.
11/84	Greater Atlanta Coalition on Health Care	Data on visits to physicians.
1/85	Veterans Affairs Branch	Per capita total expenditures for veterans, and Medicare and out-of-pocket costs for this group using income and age as control variables.
Spring 86	Rutgers University	Analyzed data on Medigap insurance by division for legislation.
8/85	Duke University	Estimates provided on uninsured poor in North Carolina.
2/85	Duke University	Analyzed expenditures for health services and sources of payment for poor in South vs. rest of country.
12/85	California Legislature	Provided estimates of divorced women and health insurance coverage.
12/85	California Legislature	Estimated Medicaid expenditures and use by race.

3/85	Michigan Legislature	Analyzed state risk poors for employed, unemployed, and uninsured.
12/86	New York State	Provided assistance on data collection of information on autistic children.
12/86	American Academy of Pediatrics	Insurance status of children.
12/86	American Health and Management	Estimated dental insurance by region.
10/85	Pennsylvania Blue Cross-Blue Shield	Small area estimation.
10/85	Oklahoma Hospital	Analyzed for South Central Region percent of persons with physician visits and chronic conditions by poverty status.
4/85	State of Connecticut Department of Aging	Estimated elderly expenditures by sources of payment.
9/85	Maryland State Government	Medicaid expenditures and use by race.
6/85	Illinois	Analyzed uninsured and private benefits by division.
5/85	Nationwide Rural Health Association	Tables on medically indigent and uncompensated care.
5/85	New York State	Estimates of underinsurance.
10/85	Pennsylvania	Analysis of private health insurance by Census Region.
6/85	New York State Medicaid and Department Social Service	Provided review of research long-term care insurance.
3/86	Rhode Island State Government	Presentation on private sector initiatives in long-term care.
4/86	State of Georgia	Discussion of private initiatives in long-term care insurance and plans for research assistance.
3/85	National Association of Insurance Commissions	Briefing on research findings related to long-term care insurance.

12/85	American Hospital Association	Findings from research on long-term care insurance.
3/85	Health Care Financing Administration	Tables and findings from NCHSR Nursing Home Incentive Experiment.
5/85	National Association of States Units on Aging	Research findings on long-term care insurance.
5/85	State Conference University of Massachusetts	Presented findings from NCHSR Nursing Home Study.
10/84	Vermont Department of Health	Provided resources to develop data tapes on hospital use and service areas for the state.
11/85	Maryland Department of Health	Consulted on how Maryland hospital data could be used for policy research and shared NCHSR research on Maryland hospitals.
9/85	Connecticut Legislature	Provided assistance on DRGs and severity of illness measures, as basis for a prospective payment system for hospitals in Connecticut.
3/86	New York Department of Health	Obtained hospital abstract and billing data to analyze DRG issues.
1/86	RAHC and FLAHC	Initiated a study of New York hospitals to assist the Rochester Area Hospital Corporation and the Finger Lakes Area Hospital Corporation in evaluating a reimbursement demonstration.
6/85	State Officials	Presented the research findings of the Intramural Research Program on the use of hospital services, health technology, and hospital capital financing to health department officials and legislative staff from Connecticut, Florida, Maine, New Hampshire, Pennsylvania, Rhode Island, South Carolina and Vermont.
3/85	Oregon SHPDA	Prepared a summary of empirical research findings

		on the cost of empty hospital beds for the Director, State Health Planning and Development Agency.
2/85	Commissioner of Health Tennessee	Reviewed research on uncompensated care.
1/85	Illinois Hospital Cost Containment Council	Provided information and assistance to the staff on hospital financial data bases.
3/86	Connecticut Department of Mental Health	Consulted on the use of and problems with hospital discharge abstract data.
10/84	University of Pittsburgh	Prepared means and standard deviations of charges by DRG from Maryland data for analytic project.
12/84	Centers for Disease Control	Provided a computerized DRG translation algorithm for old disease classification coding systems.
11/84	Health Care Financing Administration	Provided Sole Community Hospital analysis for use in report to Congress.
11/84	University of California	Provided information on hospital characteristics to support university research project.
10/84	AMA	Consulted on AMA Masterfile Survey revisions in relation to the research community's needs for physician data.
10/85	Congressional Budget Office	Consulted on Disease Staging and provided various NCHSR analyses.
12/84	Business Coalitions in Atlanta & Detroit	Provided information on hospital financial position and capital reimbursement.
10/84	Illinois Hospital Association	Provided information on hospital financial positions and capital reimbursement.
10/84	Iowa Health Care Cost	Provided information on hospital financial position.

PAPERWORK BURDEN

Mr. O'Brien. In my district in Illinois, we have six hospitals where approximately 29 percent of the admissions are under Medicare. Perhaps that is not a lot of Medicare admissions, but doctors and administrators tell me that the paperwork associated with that 29 percent takes up 50 to 60 percent of their paperwork chore. Do you project any effort on the part of the Department to bring the paperwork blizzard under control?

Secretary Bowen. We have undertaken a number of efforts to reduce paperwork for hospitals and physicians. The most important is the introduction of common claims forms for inpatient hospital and physician services. The form 1450 is used by almost all third party payers for inpatient hospital billing. This allows facilities to only complete one form for Federal, State and private payers.

In addition, HCFA has developed a common claim form for physician services. The form 1500 can be used like the 1450 for many third party payers.

Mr. O'Brien. Dr. Bowen, as medical technology improves, life expectancy lengthens, as treatment expectations rise, and as medical problems shift with age - should the Department be adapting its regulations to account for differing Medicare populations that must be served?

Secretary Bowen. The Medicare program will pay for all covered medical services that are reasonable and necessary for a beneficiary. We believe that provides maximum flexibility for the patient's physician to prescribe what that patient needs. When the Medicare statute was amended in 1972 to include persons who had been disabled for at least 2 years and persons with end stage renal disease, the broad precept stated above applied equally. If we changed the rules (which we believe can be done only by Congress) to provide different benefits to persons of different ages, where would we draw the distinctions -- 70? 85? As the medical problems shift, the physician may shift the treatment. As new technology is proven safe, the physician may prescribe them for the patient regardless of age. We firmly believe physicians should treat individual patients rather than categorize them into age or any other kind of group.

NURSING RESEARCH

Mr. Pursell. Assuming the proposed rescission of Nursing Research Grants does not go into effect, will the approved Nursing Research Grants that had delayed review in 1985 receive priority among the new grants?

Secretary Bowen. Priority scores of approved unfunded FY 1985 projects will be interdigitated with those successfully competing in FY 1986 and new awards will be made from this interdigitated listing as available funds permit.

Mr. Pursell. For the record, would you please provide the past and anticipated funding rates -- assuming no fiscal year 1986 rescission -- for fiscal years 1984, 1985, and 1986 for new, competing renewal, and non-competing renewal Nursing Research Grant applications?

Secretary Bowen. The following funding information for nursing research grants is provided:

Funding for Nursing Research Grants
FY 1984 - FY 1986

	New/Renewals		Non-competing Continuations		Total	
	No.	Amount	No.	Amount	No.	Amount
FY 1984	46	$4,192,998	38	$4,712,893	84	$8,905,891
FY 1985	33	$3,628,054	57	$5,771,946	90	$9,400,000
FY 1986(est)	23	$2,350,000	66	$6,933,000	89	$9,283,000

Mr. Pursell. Would you please provide for the record information for fiscal years 1983, 1984, 1985 and 1986 concerning the number of new, competing renewal and non-competing renewal Nursing Research Grant applications, by date of submission, according to: the number approved for each fiscal year, the number funded for each fiscal year, and the range of priority scores funded for each fiscal year?

Secretary Bowen. The following tables summarize Nursing Research applications received and the number of awards made:

Number of Nursing Research Grant Applications Received
FY 1983 - FY 1986

	Grant Applications Received		
	New Renewal	Non-Competing Continuations	Total Received
FY 1983......	98	14	112
FY 1984......	208	38	246
FY 1985......	229	37	266
FY 1986......	302	47	349

Number of Nursing Research Grants Funded
FY 1983 - FY 1986

	Competing New/Renewal Approvals	Competing New/Renewal Awards	Non-Competing Continuation Awards	Total Awards*
FY 1983......	31	38**	14	52
FY 1984......	57	50	38	88
FY 1985......	[illegible]	33	57	90
FY 1986......	111	23	57	80

* The range of priority scores for grants awarded is between 100-[illegible].

** Includes 7 approved and previously unfunded grants from FY 1982.

Mr. Pursell. According to recent data collected by the American Association of Colleges of Nursing, enrollments in generic baccalaureate nursing programs have declined 7.6 percent between fall 1984 and fall 1985. Nursing shortages are once again being felt and are predicted to become more problematic due to decreasing enrollments. Federal support is critical to the survival of many nursing programs, and the President's budget proposes rescission of most of the Division of Nursing 1986 funds and total elimination of oversupply statistics pertinent to physicians do not apply to nursing. Therefore, what rationale does the Administration have for rescission and then elimination of funds for nursing education and research?

Secretary Bowen. The most reliable information regarding trends in admissions and enrollments in schools of nursing is provided by the Annual Survey of the National League for Nursing covering all schools of nursing. The latest information is for the academic year 1983-84 in which admissions of generic students to baccalaureate programs increased by 5.7% over the previous year. Total enrollments are a less reliable indicator of trends because they are affected by numerous factors such as changes in length of program and attrition rates. Evidence presented in the Fifth Report to the Congress on the Status of Health Personnel in the U.S. found no aggregate imbalance between supply and requirements in the foreseeable future. Profound changes in the health care delivery system could alter the supply-demand equation, but there is no quantifiable evidence to date to document the impact of such changes.

Mr. Pursell. what evidence does the Administration have indicating that other funding sources are available to replace Federal funding for nursing education and research?

Secretary Bowen. The past twenty years of federal support has substantially increased the capability of schools of nursing to add to the nurse supply. Baccalaureate programs are now firmly established in academic settings and have available to them the same resources as are used for other health disciplines.

Mr. Pursell. In 1983 your predecessor, Mrs. Heckler, established a Center for Nursing Research in the Division of Nursing. However, no funds were made available by the Administration to establish the center. The Congress mandated the establishment of a National Center for Nursing Research at NIH in P.L. 99-158. Now, the Administration proposes a total rescission of the $5 million dollars appropriated by Congress to establish the new center-P.L. 99-88. What is your rationale for proposing this rescission in light of a clear Congressional mandate to authorize and appropriate funds for the National Center for Nursing Research and in light of a serious evidence of need for nursing research funds according to a 1983 Institute of Medicine study?

Secretary Bowen. The rescission request is a part of the President's overall budget reform plan to curtail Federal Government spending. Taking into account the future projections of requirements and the available supply, and given the anticipated flow of graduates and current trends in the work patterns of the registered and licensed practical nurse population, the Administration continues to believe that no aggregate shortage exists, nor or in the foreseeable future. Therefore, rescission of these funds is desirable.

Mr. Pursell. A 1983 Institute of Medicine (IOM) report concluded that nurses with high-quality graduate education are a scarce resource. The report recommended an increase in the number of nurses with skills commensurate with -- the growing complexity of care in many health settings. The Administration contends that there is an adequate supply of registered nurses in the country. The nursing education monies are not targeted to increasing the number of general nurses. However, they are targeted to preparing nurses at the masters and doctoral levels. There is clearly not an adequate supply of nurses prepared at the advanced levels such as nurse midwives, nurse practitioners, nurse anesthetists, nurse researchers and clinical nurse specialists in geriatrics. How can the Administration ignore the IOM recommendations and propose elimination of Federal funding for advanced nursing education programs?

Secretary Bowen. Individuals undertaking advanced nurse education have an earning capacity and during times of Federal fiscal contraints, can be expected to finance their further education and seek support from other Federal and non-Federal sources.

Mr. Pursell. In the 1984 *Fourth Report to the Congress on the Status of Health Personnel* the Department of Health and Human Services recommended continued Federal support for nursing education programs, in the words of the report, -- to assist in filling the unmet needs for nurses prepared as teachers, administrators, or clinical specialists. How can the Department reverse its position on this issue by allowing the Administration 1987 budget to eliminate Federal funding for nursing education programs?

Secretary Bowen. The Administration must always reevaluate competing priorities for Federal support. In view of the past Federal investment in advanced nurse education training, we believe that these programs have been institutionalized into the nursing educational system and will be available for those individuals desiring to become teachers, administrators or clinical experts.

Mr. Pursell. On August 16, 1985, President Reagan signed a three-year authorization of funding under the Nurse Education Act. How can the President now propose complete elimination of those same nursing education programs?

Secretary Bowen. In its reevaluation of competing priorities, the Administration was mindful that the past twenty years of Federal support had built and stabilized an infrastructure that should enable the institutions to continue these programs into the future. Using these resources, we believe the initiative and interest generated by the Federal start-up grants will be maintained by the colleges, universities and hospitals that are responsible for training nursing students.

Mr. Pursell. Congress authorized and appropriated monies for new nursing demonstration projects to address concerns about access to nursing services. Has this program been implemented yet?

Secretary Bowen. The program has not been implemented, pending the outcome of the proposed rescission.

Mr. Pursell. How can Federal support for nursing research be eliminated when it has been shown to save taxpayer's dollars in the long run? For example, nursing research on the care of premature infants resulted in treatment that reduced their length of hospital stay by an average of four days. The average cost of neonatal intensive care is estimated to exceed $11,000 and almost 7 percent of newborns in the U.S. are at risk because of low birthweight.

Secretary Bowen. Elimination of a line item for support of nursing research should not be viewed as an assessment by the Department that studies supported previously were ineffective. Well done studies like the one you described should continue to compete successfully for research support from NIH, ADAMHA, or NCHSR.

Mr. Pursell. A 1983 Institute of Medicine report expressed strong reservations about the under-funding of nursing research. In addition, a recent study of nursing research prepared for the Office of Health Planning and Evaluation, Office of the Assistant Secretary for fHelth, United States Public Helth Service, commented on the negative impact of erractic funding for nursing research. In light of these conclusions, shouldn't the Administration be asking for increased funding for nursing research rather than proposing its elimination?

Secretary Bowen. The Administration must always reevaluate the need for continuing support for numerous competing priorities.

NATIONAL CENTER FOR NURSING RESEARCH

Mr. Pursell. NIH staff are moving ahead to develop a Legislative Implementation Plan for the new National Center for Nursing Research. If 1986 funding for the Center is to be rescinded and elimination of funding is to be effected in 1987, what are the Administration's plans, including timetables, to establish the new Center?

Dr. Bowen. The timetable for establishing the new Center is dependent upon the resolution of the President's rescission package pending before Congress. The NIH would expect to initiate a Search and Screen Committee to identify an NCNR Director as soon as the request to establish the position is approved.

Mr. Pursell. Where are you in establishing the National Center for Nursing Research and what have you requested for the Center?

Dr. Bowen. The NIH is taking what action it can to implement the Section of P.L. 99-158 that establishes the National Center for Nursing Research, pending resolution of the President's rescission package by Congress.

Mr. Pursell. A National Center for Nursing Research was established by Congress in November 1985 through the National Institutes of Health reauthorization bill. The President's veto of the measure was overridden by votes of 380 to 32 in the House and 89 to 7 in the Senate. Doesn't this overwhelming vote clearly reiterate the support of Congress to continue to fund nursing research at the Federal level?

Dr. Bowen. The Congress made its support of the new Center very clear in its override vote last year. In the face of serious Federal deficits, however, some difficult decisions had to be made by the Administration in the development of the FY 1987 budget. The funding of nursing research at the Federal level was not considered to be of sufficiently high priority to merit support at this time of fiscal restraint.

Federal Payments to Home Health Agencies

Mr. Pursell: A 1985 preliminary report from the United States General Accounting Office which addressed the impact of the Medicare prospective payment system on post-hospital care stated that there has been an increase in the use of home health care services by Medicare beneficiaries. How can Federal payments to home health agencies be limited when the need for post-hospital care is greater than ever?

Secretary Bowen: I want to emphasize that we are not proposing to reduce Medicare funding of home health care. In fact, we are projecting that home health expenditures will increase almost 14 percent in FY 1987, even with the payment reduction mandated by the Gramm-Rudman-Hollings deficit reduction legislation.

Our home health cost limits proposal aims to control the increase in home health expenditures which have grown, since 1981, at an average compounded rate of over [illegible] percent a year. Our new cost limits are the first update of the cost limits since 1979 and reflect congressional direction to apply the rates by type of home health visit. By setting the cost limits for the first year at a generous [illegible] percent of the mean (and at 115 percent for [illegible] and [illegible] percent for [illegible]), we are providing home health agencies a transition period to improve their operating efficiency. We do not expect the cost limits will reduce access, and, in fact, we expect to see a continuing growth in the number of participating agencies relevant to the demand for services. Since [illegible], the number of home health agencies has grown from [illegible] to the current level of almost 6,000.

We are also proposing legislation to ensure that only necessary and covered services are being provided. In the past, a study by the General Accounting Office, followed by a later study which we performed, showed that [illegible] one-third of home health visits reviewed were either not medically necessary or were not covered under the Medicare program.

Further, we are proposing that a [illegible] copayment per visit [illegible] be required for [illegible] visits [illegible] than [illegible] a patient [illegible] inpatient hospital or skilled nursing facility. [illegible] home health services [illegible] the [illegible] benefit [illegible] or [illegible] beneficiaries or physicians to consider the necessity of continuing visits. [illegible] copayment is intended to provide [illegible] incentives without [illegible] home health care [illegible] a SNF.

Consequently, we do not [illegible] proposals will [illegible] adverse impact on [illegible] necessary, [illegible] health care.

Mr. Pursell: Isn't it unwise to propose reductions in Medicare funding that may have an impact on the ability of hospitals to continue to provide access to health care services and to maintain adequate staffing levels which could affect the quality of care patients receive?

Secretary Bowen: Taking into account all our proposals for FY 1988, Medicare payments to hospitals will still increase slightly in FY 1988. When considered with recent reports by the General Accounting Office and the hospital industry of the increased profitability hospitals are experiencing, presumably resulting in large measure from PPS incentives to cost-effective operations, we believe efficiently managed hospitals will not find it necessary to take actions that limit access or reduce quality.

Although we have heard anecdotal incidences of poor quality care, we have seen no evidence that a system-wide problem exists. The Peer Review Organizations will continue their duties to assure that only medically necessary care of high quality is provided to Medicare beneficiaries.

It is impossible to estimate the impact of this system compared to the system which would have been in effect had there been no prospective payment. There were no decisions made on how the other system would operate and no estimates of the costs of that system. I can say that it is apparent health care costs have moderated. When this Administration took office, health care costs were rising at a rate of fifteen percent a year. In 1986, the increase in health care costs had declined to about nine percent.

BIOMEDICAL RESEARCH

Mr. Porter. Mr. Secretary, your budget request includes a sizable cut for the National Institutes of Health. What impact will such a cut have on research projects which are ongoing and nearing completion at NIH?

Dr. Bowen. All research project grants with outyear commitments for FY 1987 will continue to receive support. However, given budgetary constraints, the FY 1987 request will require downward negotiations for these noncompeting continuations of approximately 9 to 10 percent from committed amounts. It is expected that some of the reduction will be achieved through developing greater efficiency, especially in the area of personnel and in the purchase of supplies and equipment. In addition, the research projects will also have to be scaled back from study section recommendations.

Mr. Porter. Given the unique nature of research funding, did the Department carefully consider the disruptive impact that such cuts would have?

Dr. Bowen. Every effort will be made to mitigate any adverse impact of the reductions reflected in the FY 1987 request. For example, the Administration is proposing a new, redefined stabilization policy for research project grants in FY 1987 that encompasses noncompeting as well as competing research project grants. This new policy recognizes that NIH, because of budget constraints, cannot continue to fund 6,100 competing research project grants in FYs 1986-1987 without seriously compromising the adequate funding of other NIH mechanisms and NIH's ability to maintain a balanced program. The new stabilization policy for NIH will support a total grant level of 18,000 awards beginning in FY 1987.

In addition, in order to provide a smooth transition from FY 1985 to FY 1987, the FY 1986 revised estimate reflects a proposed rescission of $55.7 million, which will reduce the number of competing research project grants by approximately 600 awards, from 6,100 to 5,500 grants. This proposal would permit NIH to achieve the new stabilization policy of 18,000 total research projects without drastically reducing the number of competing awards in FY 1987, or diverting funds from the other NIH mechanisms in the FY 1987 request. The total number of research project grants supported in the FY 1986 revised estimate is 18,195. In comparison, the FY 1986 appropriation provided support for 18,770 research project grants.

Mr. Porter. How exactly are the recently implemented Gramm-Rudman cuts being administered at NIH? Is there enough flexibility to allow the individual Institutes to prioritize major research projects within each jurisdiction? Or are the 4.3 percent cuts being administered uniformly across each line item? Shouldn't each Institute be allowed to set its own priorities?

Dr. Bowen. As a result of the Balanced Budget and Emergency Deficit Control Act, the FY 1986 appropriated level for NIH has been reduced by about $216 million. This reduction has been applied against the total amount appropriated to each Institute as well as against each research mechanism at the NIH aggregate level, and each identified program, project, and activity. At the year progresses, the Institute Directors will carefully monitor the research opportunities in each of these areas, and will propose reprogrammings as necessary, to assure that their highest priority activities are adequately funded.

VOLUNTARY FAMILY PLANNING

Mr. Porter. Would you favor a policy mandating that government funded family planning clinics promote only one form of contraception?

Secretary Bowen. No, sir. Users of family planning should have options in choosing the family planning method which best suits them. Requiring provision of a range of family planning methods insures that the client and the service provider can choose the method that the client prefers and which best suits the clients's particular needs. I do think it makes sense to use single-service providers for complex specialized services like infertility and natural family planning, but services provided in this fashion are administered under subcontract from a full service Title X grantee.

HEALTH PLANNING

Mr. Porter. Mr. Secretary, your own State of Indiana has eliminated health systems agencies. Other States have elected, in increasing numbers, to drop their participation in the Federal health planning program. Congress is now considering whether or not to repeal the Federal health planning program, or extend it. The House recently H.R. [illegible] which repeals Federal health planning as of October [illegible], 1986. Where do you and the Administration stand on the repeal of Federal health planning legislation?

Secretary Bowen. The Administration has consistently advocated since 1981 the elimination of the health planning program as currently operated. With the reform of hospital capital expenditures through the Medicare reimbursement system, the need for continuing the procedural review requirements of the health planning program becomes even less [illegible].

Prospective Payment System (PPS) Rates

Mr. Porter: Over the past couple of years, inflation has increased by roughly 7-8 percent. Yet, under the PPS, payment rates to hospitals will have increased only 2.5 percent. How does this affect a provider's ability to provide quality care?

Secretary Bowen: The PPS was enacted by Congress as a means of changing hospitals' incentives under Medicare to provide cost-effective, high quality health care. The President's FY 1987 budget assumes that the PPS rates will be increased by 2 percent. This 2 percent factor is considered a placeholder, the true update factor will be established by the Department after consideration of the PROPAC recommendations and other required analyses. As you know, the update is a measure of many factors, both cost increasing and decreasing, affecting hospital costs such as inflation, productivity and technology. Therefore, when an update is less than inflation, it is because changes in hospital behavior have led to reduced costs.

Since PPS has been in place, we have seen improvements in productivity and in technology that have had a beneficial impact on hospital costs. Therefore, rates have increased at less than the inflation rate. In fact, hospital costs during this period have increased only 5-6 percent. Further, our studies indicate that since PPS, the quality of care rendered to Medicare beneficiaries has remained high. We are aware of anecdotal evidence of quality of care suffering because of incentives to contain costs under PPS. Although the Department is looking into such allegations, we have not found any concrete evidence of a reduction in the quality of care.

Catastrophic Health Insurance

Mr. Young: Mr. Secretary, as you well know, Medicare and health care costs in general are of great concern to my constituents in Pinellas County, Florida. They were pleased to hear President Reagan restate his support for catastrophic health insurance in his State of the Union address and I am pleased to know that someone with your background in this area is leading the effort to institute such a plan. How is your health insurance study progressing and when will your report be available?

Secretary Bowen: I will be asking a thirteen-member Private/Public Sector Advisory Committee to seek public input on the problem of catastrophic illness and react to the development of options and recommendations to submit to the President in December 1986. Within the Department, an executive committee of senior staff will review and make decisions on options prepared by three Technical Work Groups (TWGs). The scope of the TWGs is generally as follows:

- o Catastrophic illness in the general population,
- o Acute catastrophic illness in the over-65 population, and
- o Private financing of long-term care.

I am requesting my staff to submit a draft of the Department's report to me in September 1986. I plan to present a final report to the President by December 15, 1986.

Mr. Young: I understand you conducted a catastrophic health insurance study of your own last year prior to your nomination as Secretary. In your plan, you proposed raising Medicare Part B premiums by $14.[illegible] per month to cover the cost of catastrophic health insurance. This would almost double the current Medicare Part B premium. Given the Administration's separate proposal to raise Medicare Part B Premiums from $15.50 per month under current law, to $30.00 per month by 1991, I'm concerned that an added premium increase to pay for catastrophic health care might be too great of a burden for older Americans living on fixed incomes. Is this a valid concern, and if so, what other catastrophic health care financing mechanisms might be available?

Secretary Bowen: The Administration's fiscal year 1987 budget proposes a gradual change in the Medicare Part B premium. When Part B was first established, premiums paid by individuals beneficiaries represented 50 percent of estimated program costs, with the remainder of these costs subsidized by annual general fund appropriations. Between 1974 and 1982, however, the Part B premium was allowed to grow no faster than the Social Security cost-of-living adjustment. As a result, premiums financed less than 25 percent of program costs in 1982, with general revenue appropriations financing over 75 percent of these costs. With the Administration's proposed budget, in calendar year 1987, the monthly premium would be increased by $.90 above the current law premium of $17.80.

I have proposed financing catastrophic illness coverage through an added Part B premium to spread the costs over all 30 million Medicare-enrolled beneficiaries. Such a proposal would be an advantage to all beneficiaries.

In the study currently underway by the Department, various financing and design options for catastrophic illness coverage will be examined. For example, premium financing for catastrophic Part A benefits only would require a much smaller premium amount. Analyzing proposals to set premiums by income levels may be another option.

MEDICARE PROSPECTIVE PAYMENT SYSTEM

Mr. Young. Mr. Secretary, I'd be interested in your opinion, as a doctor, about the Medicare prospective payment system. I have received letters of concern from my constituents who say they have been discharged early under this new payment system. Various studies in the last year have also concluded that Medicare patients in many cases are being discharged too early and in poorer health than prior to the prospective payment system. Have you found this to be the case?

Secretary Bowen. As expected, the average length of stay has declined since the implementation of the prospective payment system much as it has for patients under age 65. There is an incentive for hospitals to eliminate marginal services. However, we have no evidence that there is a system-wide problem with more patients being discharged prematurely than prior to the implementation of the prospective payment system.

The Health Care Financing Administration, in conjunction with the Assistant Secretary for Planning and Evaluation, is initiating a major study which focuses on developing a reliable method for assessing whether Medicare patients' are being appropriately discharged from the hospital. Specifically, this study will assess patients' health status and dependency at discharge and evaluate the adequacy, accessibility, and use of post-discharge services.

Additionally, HHS is conducting research into a broad range of issues related to quality and access to care under PPS. Some of these include: possible changes in patient care outcomes associated with PPS, appropriateness of lengths of hospital stays and treatment patterns, and access to post-discharge sub-acute services. While hospital length of stay dropped significantly in FY 1984, the year in which the Medicare Prospective Payment System (PPS) began to be phased in, there is no evidence available, to date, indicating a systematic change in the quality of care associated with PPS implementation. We note that length of stay and other measures of hospital use have dropped for the population under 65 -- and that this trend can indicate enhanced patient outcomes (e.g., lower risk of hospital-induced infection).

Mr. Young. A second concern that has been raised about this new payment system, especially in Florida, is that because of shorter hospital stays and in some cases early discharges, Medicare patients leaving hospitals are increasing the demand for nursing home and home health care services. This is a particular problem in Florida where there already existed a great demand for these type of health care services. Have you found this to be a problem since the prospective payment system was begun?

Secretary Bowen. The way health care is delivered in this country is changing rapidly for all patients and for all payment methods. For example, less inpatient care is being delivered and the length of stay for inpatient care is declining for all patients--not just for Medicare beneficiaries. Other factors influencing the use of nonhospital services are that people are living longer and new technologies are prolonging life, but frequently rendering patients in a more dependent state.

Current data on the number of long term care facilities which participate in Medicare and Medicaid indicate that there are approximately 17,000 skilled nursing and intermediate care facilities nationwide. The universe has remained fairly constant over the past few years (i.e., in the past 5 years, there has been a 2 percent per year increase).

The number of hospital-based home health agencies has increased dramatically from 507 in 1982 to 1,179 in 1985 (an increase of 132 percent). The total number of home health agencies (i.e., freestanding and hospital-based) increased 165 percent during that period. The increase in hospital-based home health agencies maximizes access to home health care for many Medicare beneficiaries making the transition from acute hospitalization. We have no knowledge that beneficiaries seeking home health care have found it unavailable. As of January 30, 1986, there are 5,975 home health agencies participating in Medicare. A number of these have branches and subunits thereby increasing the areas in which home health agency services are offered.

HEALTH MAINTENANCE ORGANIZATIONS

Mr. Young. I am interested in your opinion about the quality of care older Americans are receiving through health care maintenance organizations. The Tampa Bay area in Florida was one of the test areas for Medicare HMO coverage. I have received letters from constituents who say that HMOs have not delivered all the advertised services and have questioned the quality of their care. We have also seen in Florida cases where HMOs have gone out of business or been unable to pay their bills in a timely fashion. Are HMOs a viable health care alternative for older Americans depending on Medicare?

Secretary Bowen. Prior to April 1985, two HMOs (International Medical Centers (IMC) and AV-Med) operated as demonstration projects in the Tampa area. The Office of Research and Demonstrations (ORD), which monitored the demonstrations, was aware of a few complaints about quality of care received in one particular clinic at IMC HMO. They were not aware of any complaints about HMOs not delivering advertised services. None of the demonstration HMOs went out of business or were unable to pay their bills.

The quality of care complaints were investigated by ORD staff. IMC was asked to submit a written assessment of its investigation with a corrective action plan. Information was sent by IMC's Director of Quality of Care, which satisfactorily addressed each complaint. Staff from the Office of Health Maintenance Organizations (OHMO) in PHS subsequently made site visits to Tampa sites as part of their quality assurance compliance process for Federal qualification. We understand that IMC satisfied all requirements.

ORD is now conducting a comprehensive evaluation of the Medicare HMO demonstrations. Since the demonstrations converted to the regular TEFRA program early in 1985, the evaluation findings will also apply to operating periods under TEFRA. A key component of the evaluation is an analysis of the quality of care received in HMOs. Under the contract, quality of care will be addressed in three separate reports to HCFA: (1) An evaluation of access to care, the quality of the process of care, and outcome of care, including - a direct process assessment utilizing review of individual beneficiary medical records from the plans and fee-for-service providers, with analysis of routine care provided (e.g., immunizations), routine conditions (e.g., hypertension), and high morbid conditions (e.g., cancer); a comparison of enrollee and non-enrollee access to care; and an indirect assessment of the outcome of care, utilizing an analysis of differences in patterns of health status between enrolled and comparison site beneficiaries overtime; (2) a description and analysis of quality assurance programs as constituted and utilized by the plans; and (3) an evaluation of satisfaction with care between enrollees in risk-based plans and comparison site users of the fee-for-service system.

The report on process of care is due December 1987; the report on the analysis of quality assurance programs is due June 1986; and the report on initial beneficiary satisfaction is due September 1986.

All HMOs make those services that are contained in the contract with HCFA available to all enrollees. Problems relative to misleading or deceptive advertising usually surface in the marketplace. When these occur, we contact the affected HMOs in an attempt to work out the problems. In fact, this has happened before, and we have been successful in effectuating a resolution. However, since the regulations do prohibit certain marketing practices, HCFA could always terminate the contracts should the need arise, e.g., plans continued use of misleading advertising.

We believe that the complaints concerning payment of bills in a timely manner are confined primarily to one particular HMO. Generally, an HMO must, in fact, pay its bills in a timely manner in order to effectively compete in the marketplace and to be able to negotiate sound contracts with its providers, suppliers, and other vendors. We receive very few complaints of this type and they have been limited to only a few HMOs. Nevertheless, we are amending the contracts that we sign with HMOs to include timeliness standards.

Based upon those reviews we have conducted to date, we have found that the overall complaint rate of HMO enrollees has been the same, and in some cases, even lower than the complaint rate of the fee-for-service.

Finally, I emphasize that HMOs/CMPs are an alternative health delivery system expected to exist alongside the fee-for-service systems. Medicare beneficiaries are being advised of the existence of HMOs/CMPs and offered a choice of health care delivery systems. Because of the escalation in the costs of health care in the U.S., individuals and organizations are looking for other less costly ways to provide these services. Prepaid health plans are seen as a promising alternative, and therefore, have had considerable growth in the past few years.

PHYSICIAN FEE FREEZE

Mr. Young. Shortly after you took office, I read where you were concerned about a proposal to extend for a second year the freeze on Medicare physician reimbursement fees. You specifically noted that such a freeze might result in lower quality medical care. I have also been concerned about physician reimbursement freezes, because I'm afraid that such freezes would discourage doctors from seeing Medicare patients. This would be a particular problem in my part of Florida where there is such a high percentage of Medicare patients. Do you support a freeze on Medicare physician reimbursement fees and would such a freeze result in lower quality and less available medical care for Medicare patients?

Secretary Bowen. When discussing the merits of extending the freeze, it is important to keep in mind what has happened to budget outlays for physicians' services since this Administration has been in office. During the period of FY 1981 to FY 1985, a period that included the original 15-month fee freeze, budget outlays for physicians' services grew at an average annual compounded rate of 15 percent. This is greater than the rate of increase for the budget as a whole or even for national defense. During FY 1985, under the freeze, the rate of increase in spending for physicians' services continued to outpace the increase in the physician services component of the Consumer Price Index.

We have seen no evidence of a deterioration of quality or access as a result of the freeze. In fact, during the freeze, we have seen a dramatic increase in the percentage of program dollars paid under assignment. In the State of Florida, in the October - December quarter, assignment increased by 15.2 percent in FY 1985 and by 9.7 percent in FY 1986. As of the first quarter of this fiscal year, 68.1 percent of program payments in Florida were accepted on assignment.

The President's FY 1986 budget proposed a continuation of the fee freeze for another year. Congress has extended the freeze through March 14th. We see no reason to change our position and would therefore support an extension of the freeze through the remainder of this fiscal year.

MEDICARE PREMIUMS AND DEDUCTIBLE

Mr. Young: [illegible], the cost of Medicare coverage is an important concern to the people I represent. The Administration proposes raising Part B premiums from [illegible], under current law, to [illegible] by [illegible], a [illegible] percent increase over five years. I'm concerned that [illegible]. What do you think?

Secretary [illegible]: The proposal to increase the Part B premium [illegible] each year over a [illegible] period [illegible]. [illegible] Part B program. [illegible]

At the end of the [illegible] period, [illegible] premiums [illegible] percent [illegible]. This would [illegible] Part B [illegible] the Federal budget.

Also, [illegible] proposed [illegible] percent.

Mr. Young: [illegible] developed [illegible] legislation.

Secretary [illegible]: [illegible] average length of stay [illegible] Congress.

[Clerk's note.—The justification materials on the fiscal year 1986 rescissions proposed by the President on February 5, 1986, and referred to earlier by the Chairman, as well as the special tables and reports prepared by the Department at the request of the Committee follow:]

Justification of Rescission Estimates for Committee on Appropriations

1986

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Fiscal Year 1986 Rescissions

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HEALTH RESOURCES AND SERVICES

Of the funds made available under this head in Public Law 99-178, $206,455,000 are rescinded, and in addition, $5,[illegible] are rescinded from available balances.

Health Resources and Services

Amounts Available for Obligation 1/

1986 Appropriation	$1,497,934,000
1986 Sequester order	-49,713,000
Proposed Rescission of Budget Authority	-206,455,000
Subtotal, adjusted appropriation	1,241,766,000
Proposed unobligated balance rescinded	-5,000,000
Unobligated balance, start of year	42,439,000
Unobligated balance, lapsing	-285,000
Unobligated balance, end of year	-14,929,000
Total, obligations	$1,281,191,000

1/ Excludes reimbursements collected from Federal funds for the Health Resources and Services account.

Summary of Changes

1986 Estimate..	$1,497,934,000
1986 Sequester order...	-49,713,000
1986 Estimate after sequestering...............................	1,448,221,000
1986 Revised estimate..	1,241,766,000
Net Change..	-$211,455,000

	1986 Base Amount	Change from Base Amount
Decreases:		
A. Program:		
1. Health Care Delivery and Assistance		
(a) Community Health Centers..............	$396,[illegible]	-$21,000,000
(b) Migrant Health........	$44,946,000	-$646,000
(c) Home Health...........	$1,435,000	-$1,435,000
(d) National Health Service Corps.........	$55,984,000	-$2,445,000
(e) National Health Service Corps Scholarships..........	$2,201,000	-$2,201,000
(f) Payment to Hawaii.................	$3,156,000	-$658,000
Subtotal, Health Care Delivery and Assistance...........		-$28,385,000

	1980 Base Amount	Change from Base Amount
2. Health Professions:		
(a) Exceptional Financial Need Scholarships.................	$6,699,000	-$6,699,000
(b) Two-year Medical Osteo. School..........	$479,000	-$479,000
(c) Public Health Capitation............	$4,751,000	-$4,751,000
(d) Health Administration Grants...............	$1,476,000	-$1,476,000
(e) Public Health Traineeships...........	[illegible]	-$1,874,000
(f) Health Administration Traineeships...........	[illegible]	[illegible]
(g) Preventive Medicine Residencies...........	[illegible]	[illegible]
(h) Family Medicine General Dentistry Residency and Training................	[illegible]	[illegible]
(i) General Internal Medicine and Pediatrics..	[illegible]	[illegible]
(j) Family Medicine Departments...............	[illegible]	[illegible]
(k) Physician Assistants	[illegible]	[illegible]
(l) Health Professions Special Educational Initiatives..............	[illegible]	[illegible]
(m) Area Health Education Centers..............	[illegible]	[illegible]
(n) Disadvantaged Assistance...............	[illegible]	[illegible]

	1986 Base Amount	Change from Base Amount
(o) Health Professions Analytical Studies and Reports..................	$1,914,000	-$434,000
(p) Advanced Nurse Education..............	[illegible]	+$12,071,000
(q) Nurse Practitioner Midwife...............	[illegible]	[illegible]
(r) Nursing Special Projects.................	[illegible]	[illegible]
(s) Nursing Traineeships...	[illegible]	[illegible]
(t) Nursing Fellowships...	[illegible]	[illegible]
(u) Nursing Research Grants.................	[illegible]	[illegible]
(v) Nurse Anesthetists....	[illegible]	[illegible]
(w) Center for Nursing Research...........	[illegible]	[illegible]
(x) Nurse Demonstration Projects...........	[illegible]	[illegible]
(y) Nurse Faculty Fellowships..........	[illegible]	[illegible]
(z) Loans Guarantees....	[illegible]	[illegible]
Subtotal, Health Professions		[illegible]

	19[illegible] Base Amount	Change from Base Amount
3. Health Maintenance Organizations and Resources Development		
(a) Local Planning..............	$1[illegible]	-$11,5[illegible]
(b) State Planning..............	$[illegible]	-$[illegible]
(c) Planning Methods Development..............	$[illegible]	-$[illegible]
(d) Outpatient Facilities Construction..............	$[illegible]	-$[illegible]
(e) Direct Operations, BHMORD..	$1[illegible]	-$[illegible]
Subtotal, Health Maintenance Organizations and Resources Development..............		-$[illegible]
4. Program Management..............	$[illegible]	-$[illegible]
Net change..............		-$[illegible] 1/

1/ [illegible]

Budget Authority by Activity
(in thousands)

	1986 Appropriation	1986 Available after Sequestering	1986 Revised Estimate		1986 Proposed Rescission	
	Amount	Amount	FTE	Amount	FTE	Amount
1. Health Care Delivery and Assistance						
a. Community Health Centers	400,000,000	396,000,000	---	375,000,000	---	-21,000,000
b. Migrant Health	45,400,000	44,946,000	---	44,300,000	---	-646,000
c. Home Health Services	1,500,000	1,435,000	---	---	---	-1,435,000
d. National Health Service Corps	58,500,000	55,984,000	600	53,539,000	---	-2,445,000
e. Nat'l Health Service Corps Schol.	2,300,000	2,201,000	---	---	---	-2,201,000
f. Payment to Hawaii	3,300,000	3,158,000	---	2,500,000	---	-658,000
2. Health Professions						
a. Except. Financial Need Schol.	7,000,000	6,699,000	---	---	---	-6,699,000
b. Two-year med. [illegible] schools	500,000	479,000	---	---	---	-479,000
c. Public Health Capitation	5,000,000	4,785,000	---	---	---	-4,785,000
d. Hlth Administration Grants	1,500,000	1,436,000	---	---	---	-1,436,000
e. Public Health Traineeships	3,000,000	2,871,000	---	---	---	-2,871,000
f. Health Adm. Traineeships	500,000	479,000	---	---	---	-479,000
g. Prev. Medicine Residencies	1,600,000	1,531,000	---	---	---	1,531,000
h. Fam Medicine Dent Res & Trng	38,000,000	36,452,000	---	15,000,000	---	-21,452,000
i. Gen. Internal Med & Ped.	18,500,000	17,704,000	---	5,842,000	---	-11,862,000
j. Family Medicine Departments	7,000,000	6,699,000	---	---	---	-6,699,000
k. Physician Assistants	4,800,000	4,594,000	---	---	---	-4,594,000
l. Hlth Prof Special Educ. Init.	8,000,000	7,656,000	---	---	---	-7,656,000
m. Area Health Education Centers	18,000,000	17,226,000	---	4,743,000	---	-12,483,000
n. Disadvantaged Assistance	25,500,000	24,403,000	---	13,000,000	---	-11,403,000
o. Allied Hlth Study Training & Spcl.	4,000,000	3,914,000	---	3,500,000	---	-414,000

	1986 Appropriation Amount	1986 Available after Sequestering Amount	1986 Revised Estimate FTE	1986 Revised Estimate Amount	1986 Proposed Rescission FTE	1986 Proposed Rescission Amount
p. Advanced Nurse Education	15,455,000	14,790,000	---	2,719,000	---	-12,071,000
q. Nurse Practitioner/Midwife	12,000,000	11,484,000	---	378,000	---	-11,106,000
r. Nurse Special Projects	9,500,000	9,092,000	---	2,345,000	---	-6,747,000
s. Prof Nurse Traineeships	11,500,000	11,005,000	---	---	---	-11,005,000
t. Nurse Fellowships	2,000,000	1,914,000	---	733,000	---	-1,181,000
u. Nurse Research Grants	9,700,000	9,283,000	---	1,493,000	---	-7,790,000
v. Nurse Anesthetists	800,000	766,000	---	---	---	-766,000
w. Nurse Demonstration Projects	1,350,000	1,292,000	---	---	---	-1,292,000
x. Faculty Fellowships	550,000	526,000	---	---	---	-526,000
y. Center for Nursing Research (Non-Add)	(5,000,000)	(5,000,000)	---	---	---	(-5,000,000)
z. Direct Operations, BHPr	20,200,000	19,331,000	110	15,040,000	---	-4,291,000
Health Maintenance Organizations and Resource Development						
a. Local Planning	15,680,000	15,006,000	---	3,440,000	---	-11,566,000
b. State Planning	4,800,000	4,594,000	---	---	---	-4,594,000
c. Planning Methods Development	418,000	400,000	---	---	---	-400,000
d. Outpatient Facilities Construction	5,000,000	---	---	750,000	---	-4,035,000
e. Direct Operations, BHMORD	20,700,000	19,810,000	306	18,764,000	---	-1,046,000
Program Management	23,994,000	22,962,000	376	18,151,000	---	-4,811,000
All Other	693,362,000	678,608,000	1,201	665,258,000	---	---
Total	1,491,966,000	1,448,221,000	2,819	1,241,766,000	---	-206,455,000 (-5,000,000) 1/

1/ Includes fiscal year 1985 unobligated balance of $5 million proposed for rescission in FY 1986.

Health Resources and Services Administration

Budget Authority by Object

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	1986 Proposed Rescission
Personnel compensation:				
Permanent positions.........	$83,496,000	$79,991,000	$78,167,000	-$2,824,000
Positions other than permanent.................	11,512,000	11,349,000	11,106,000	-243,000
Other personnel compensation..............	9,833,000	9,771,000	9,696,000	-75,000
Special personal services payments..................	30,000	28,000	27,000	-1,000
Subtotal, personnel compensation.............	104,871,000	101,139,000	98,996,000	-3,143,000
Personnel benefits............	16,352,000	16,054,000	15,796,000	-358,000
Benefits for former personnel.	111,000	111,000	111,000	—
Travel and transportation of persons......................	5,321,000	5,233,000	4,579,000	-754,000
Transportation of things......	3,173,000	3,166,000	3,051,000	-115,000
Rent, communications, and utilities...................	4,553,000	4,445,000	4,198,000	-347,000
Standard level user charges...	5,021,000	5,020,000	5,016,000	-4,000
Printing and reproduction.....	716,000	708,000	634,000	-94,000
Other services................	22,614,000	21,437,000	17,416,000	-5,021,000
Project contracts.............	11,175,000	11,028,000	9,234,000	-1,794,000
Supplies and materials........	1,517,000	1,476,000	1,320,000	-156,000

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	1986 Proposed Rescission
Equipment......................	2,011,000	1,964,000	1,591,000	-473,000
Investments and loans..........	1,000,000	957,000	957,000	---
Grants, subsidies and contributions..............	1,319,499,000	1,275,513,000	1,076,817,000	-199,196,000
Total budget authority by object...................2/	$1,497,934,000	$1,446,221,000 3/	$1,241,766,000	-$211,455,000 4/
(Total obligations)...........	($1,399,081,000)	($1,517,139,858)	($1,162,143,000)	

1/ Includes the following reimbursable FTEs: 1985 - 265 FTEs; 1986 - 225 FTEs; and 1987 - 147 FTEs.
2/ Fiscal Year 1986 includes $285,000 which would lapse.
3/ Reflects a reduction of $49,713,000 pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985, P.L. 99-177 and a proposed rescission of $206,455,000.
4/ Includes fiscal year 1985 unobligated balance of $5 million proposed for rescission.

Health Care Delivery and Assistance

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
1(a). Community health centers..........	$400,000,000	$396,000,000	$375,000,000	-$21,000,000

Purpose and method of operation

This activity provides essential prevention-oriented primary care services to medically underserved populations. By the end of FY 1985 primary care services were delivered to approximately 5,200,000 medically underserved persons through Community Health Center grants. Emphasis was placed on continuing projects which demonstrated good management practices and are located in areas with demonstrated high need for Federally supported primary care services. Special attention was given to the expansion of State involvement in program funding decisions. Approximately 40 State Departments of Health have entered into agreements with the Federal Government which increased State participation in the process of determining how best to utilize Federal resources within their State. Additionally, support was provided for the costs of approximately 971 National Health Service Corps obligors who were either converted from Federal employment to or initially placed in community health centers in 1985. Approximately 200,000 additional medically underserved persons were served through the expansion of the primary care capacity of current centers or through the development of new access points.

Rationale for the Proposed Rescission

A rescission of $21,000,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending.

The proposed funding level of $375,000,000 will provide for services in high priority rural and urban areas. In addition, funds that had been anticipated to be available for reprogramming from the NHSC have been proposed for rescission.

Health Care Delivery and Assistance

1(a). Community health centers

Impact Data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Grants awarded to States (including D.C. and Puerto Rico)................................	—	—	—
Number of categorical grant awarded................................	580	550	-30
Number served..............................	5,350,000	5,150,000	-200,000

	1986 Appropriation	after Sequestering	Revised Estimate	Proposed Rescission
1(b). Migrant health centers..........	$45,400,000	$44,946,000	$44,300,000	-$646,000

Pur,ose and method of operation

The Migrant Health Center program, through project grant authority, provides primary health services to migrants and seasonal farmworkers and their families. These services are provided in Primary Care Centers, birthing centers targeted to high risk mothers and infants, and in hospitals reimbursed by the Health Care Financing Administration through an interagency agreement with BHCDA, as well as insurance and limited hospitalization programs.

In FY 1985, a total of 500,000 migrants and seasonal farmworkers were served by 125 Migrant Health Program grantees. The program also continued its environmental health assessment activities, and provided primary health care services through limited hospitalization and insurance procedures, as well as continued to emphasize the coordination of Federal, State and local resources to serve migrants and seasonal farmworkers and their families through the utilization of existing health resources. Program emphasis was continued to increase the capacity of the community to provide primary health services to migrants utilizing volunteers and the private sector.

Rationale for the Proposed Rescission

A rescission of $646,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending.

The proposed funding level of $44,300,000 is the same level as available in FY 1985. This level will support continuation of basic primary medical services at the 1985 level.

Health Care Delivery and Assistance

1(b). Migrant health centers

Impact Data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Number of grants awarded............	125	125	—
Number served.......................	500,000	500,000	--

Health Care Delivery and Assistance

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
1(c). Home health services.........	$1,500,000	$1,435,000	---	-$1,435,000

Purpose and method of operation

The Home Health Program provides grants and loans during the period of initial operation or agency expansion, for the following purposes: (1) meeting the initial costs of establishing home health agencies, (2) expanding the services available through existing agencies, and (3) training personnel. Project grants are awarded to public or non-profit private agencies and loans to proprietary entities that meet Medicare requirements for certification or agencies which intend to become certified as a medicare provider. Project grants are also awarded to public and private agencies to train paraprofessionals (including Homemaker Home Heath Aides) to provide home health services.

Rationale for the Proposed Rescission

A rescission of $1,435,500 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending.

The Administration has not proposed funding for the Home Health program in FY 1986. The Authority to continue this activity has been included in the legislation for the Preventive Health Block Grant Program since 1981. It is expected that the $1.0 billion dollars provided annually to home heath agencies from the Medicare and Medicaid programs will be more than sufficient to meet the demand for Home Health services.

Health Care Delivery and Assistance

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1(c). Home health services

Impact Data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Service grants awarded.............	17	—	-17
Training and demonstration grants awarded....................	11	—	-11

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
1(d). National health service corps....	$58,500,000	$55,984,000	$53,539,000	-$2,445,000

Purpose and method of operation

The purpose of the National Health Service Corps (NHSC) is to improve the delivery of health services in health manpower shortage areas (HMSAs) and improve access to health care in these areas by the appropriate placement of health professionals and resources.

The NHSC budget provides salaries and related payroll costs for federally employed health professionals as well as support costs required to assist communities in developing NHSC sites and to assign health professionals either as federally employed practitioners or as private practitioners under the Private Practice Option (PPO) and Private Placement Assignment (PPA) initiatives. PPO assignees are employed in non-grant funded settings located in shortage area communities which provide a sufficient economic base to support health providers as salaried employees of clinics, hospitals and group practices or as traditional fee-for-service practitioners. PPA assignees are employed as private practitioners in Community Health Centers (CHCs) or Migrant Health Centers (MHCs) where their salaries can be offset by a combination of Federal grant funds and site earnings. Employing NHSC obligors in these programs relieves the Federal government of providing direct salary support to the scholarship obligated provider and provides the health center with greater administrative control.

Rationale for the Proposed Rescission

A rescission of $2,445,000 is proposed as part of the President's overall budget reform plan to curtail Federal government spending.

The proposed funding level of $53,539,000 will provide for an end-of-year Federally salaried field strength of 571 assignees while allowing for the placement of 1,327 new NHSC scholarship obligors: 217 to the Federal field program; 187 as private practitioners under the Private Practice Option (PPO); and 793 as employees of community and migrant health centers under the Private Placement Assignment (PPA) initiative. In addition to the health professionals who will staff NHSC sites, approximately 130 obligors will staff Indian Health Service facilities. This level also provides for approximately 46 community site loans for initial development and operation of health care facilities and 20 private practice loans to assist those scholarship recipients choosing the private practice option in establishing a practice.

Health Care Delivery and Assistance

1(d). National health service corps

Impact Data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
NHSC Federally Employed Field Staff			
1. On duty start-of-year..........	539	539	—
2. (Eligible to leave)............	(335)	(335)	(—)
3. Estimated losses from NHSC sites	-185	-185	—
4. Estimated losses due to conversion to PPO..........	—	—	—
5. Estimated losses due to conversions to PP at NHSC sites.....	—	—	—
6. NHSC new scholarships..........	+217	+217	—
7. Other sources..................	—	—	—
8. End-of-year Field Strength.....	571	571	—
Private Practice Option Field Staff			
1. On duty start-of-year..........	888	888	—
2. Estimated losses	-377	-377	—
3. From new NHSC scholarships.....	+187	+187	—
4. From NHSC conversion...........	—	—	—
5. End-of-year PPO field strength.	698	698	—
Private Placement Field Staff			
1. On duty start-of-year..........	1,531	1,531	—
2. Estimated losses...............	-289	-289	—
3. From new NHSC scholarships.....	+793	+793	—
4. From NHSC conversions..........	—	—	—
5. End-of-year PP Field Strength..	2,035	2,035	—
Combined Field Strengths			
Federally employed field staff	571	571	—
Private practice option	698	698	—
Private placements	2,035	2,035	—
Combined EOY Field Strengths	3,304	3,304	—
Distribution of New Scholarships First Available for Service			
To NHSC Federal	217	217	—
To Private Practice Option	187	187	—
To Private Placement	793	793	—
To IHS	130	130	—
Total	1,327	1,327	—

Health Care Delivery and Assistance

1(d). National health service corps

Impact Data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
I. Budget Data			
Budget Authority - Total ($000)........	$55,984,000	$53,539,000	-$2,445,000
Field Operation.......	(55,037,000)	(52,625,000)	(-2,445,000)
Loan Funding (Section 335).......	(457,000)	(414,000)	(---)
Loan Funding (Sections 338(C)(e)(1) and 338E..........	(500,000)	(500,000)	(---)
II. Assignee and Service Data			
Total NHSC assignees in Federal field:	571	571	---
-Physicians	442	442	---
-Dentists	94	94	---
-Other	35	35	---
-Scholarship	431	431	---
-Volunteer (total)	140	140	---
-New Volunteers	---	---	---
Federal Assignments			
In rural areas	400	400	---
In urban areas	171	171	---
In 01-02 HMSAs	514	514	---
In 03-04 HMSAs	57	57	---
Sites staffed	345	345	---
PPO/PP Assignments	2,733	2,733	---
In rural areas	1,591	1,591	---
In urban areas	1,142	1,142	---
In 01-02 HMSAs	2,217	2,217	---
In 03-04 HMSAs	516	516	---
Sites staffed	1,823	1,823	---
Number of people served			
by Federal physicians	430,000	430,000	---
by PPO/PP physicians	2,660,000	2,660,000	---
Total people served	3,090,000	3,090,000	---
III. Federal/State Cooperative Agreements			
Number of States Participating	33	33	--
Total Funding	$4,500,000	$4,500,000	---

Health Care Delivery and Assistance

	Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
1(e). National health service corps scholarships...	$2,300,000	$2,201,000	---	-$2,201,000

Purpose and method of operation

National Health Service Corps (NHSC) Scholarships provide tuition and fee costs and monthly stipends to students in exchange for a minimum of 2 years of service as a Federal assignee of the National Health Service Corps, the Indian Health Service or as a private practitioner in a health manpower shortage area. In FY 1985, funding was provided to make 12 NHSC continuation scholarships and an additional 37 multi-year scholarship awards to former Exceptional Financial Need scholarship recipients to enable them to complete their medical education.

Rationale for the Proposed Rescission

A rescission of $2,201,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending.

The Administration has not proposed funding in FY 1986. Since the program's inception, the greatest number of scholars first available for service were placed in FY 1985. The scholarship recipients who are now in the pipeline and subsequently obligated to serve will provide a sufficient base of health personnel to meet the essential staffing requirements of the NHSC for the remainder of the decade.

Health Care Delivery and Assistance

1(e). National health service corps scholarships

Impact Data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Continuation awards.................	10	—	-10
Multi-year EFN awards...............	37	—	-37

Health Care Delivery and Assistance

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
1(f). Payment to Hawaii	$3,300,000	$3,158,000	$2,500,000	-$658,000

Purpose and method of operation

Payments are made to the State of Hawaii to partially support the cost for care and treatment of persons with Hansen's Disease. Any expenses above the appropriated funds are borne by the State of Hawaii.

Rationale for the Proposed Rescission

A rescission of $658,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending.

The proposed funding level of $2,500,000 will provide for approximately 62 percent of state of Hawaii's Hansen's Disease program cost, compared with 66 percent in FY 1985.

Health Care Delivery and Assistance

1(f). Payment to Hawaii

Impact Data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Average Daily Patient Load	110	110	---
Patient Days	40,150	40,150	---
Inpatient Per Diem Cost	\$89.19	\$89.19	---
Total Program Cost	\$4,004,823	\$4,004,823	---
Appropriation Requested	\$3,158,000	\$2,500,000	-\$658,000
Percent of estimated cost supported by request	79%	62%[1]	-17%

[1] Compared with 66% in FY85.

Health Professions Education
Authorizing Legislation - Titles III, IV, VII, VIII, of
the Public Health Service Act

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
HP Student Assistance	$ 7,000,000	$ 6,699,000	---	- $6,699,000
HP Institutional Assistance	4,600,000	4,403,000	$ 3,924,000	- 479,000
Health Promotion/Disease Prevention	11,600,000	11,102,000	---	- 11,102,000
Primary Care	66,300,000	63,449,000	18,842,000	- 44,607,000
HP Special Educational Initiatives	8,000,000	7,656,000	---	- 7,656,000
Area Health Education Centers	18,000,000	17,226,000	4,743,000	- 12,483,000
Disadvantaged Assistance	25,500,000	24,403,000	13,000,000	- 11,403,000
Health Professions Analytical Studies and Reports	2,000,000	1,914,000	1,500,000	- 414,000
Nursing	63,900,000	61,152,000	8,668,000	- 52,484,000
Direct Operations	20,200,000	19,331,000	15,040,000	- 4,291,000
Total	227,100,000	217,335,000	65,717,000	-151,618,000

Health Professions Student Assistance:
Authorizing Legislation - Section 758(d) of the Public Health Service Act. 27

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Exceptional financial need scholarships	$7,000,000	$6,699,000	---	-$6,699,000
TOTAL	7,000,000	6,699,000	---	- 6,699,000

Health Professions

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(a). Exceptional financial need scholarships...	$7,000,000	$6,699,000	---	-$6,699,000

Purpose and Method of Operation

This scholarship program assists persons with exceptional financial need to enter a health professions school (medicine, osteopathy, dentistry, veterinary medicine, optometry, podiatry, and pharmacy). These scholarships provide financial support for full-time students in their first-year of post-baccalaureate study. Funds are allocated to participating accredited health professions schools which in turn are responsible for selecting the students who receive the scholarships. Priority is given to schools of allopathic and osteopathic medicine, and dentistry. Recipients receive monthly stipends for living expenses, plus tuition and other reasonable educational expenses, without incurring a service obligation.

Rationale for the Proposed Rescission

A rescission of $6,699,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Impact Data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Program amount	$6,699,000	---	-$6,699,000
Number of recipients	391	---	-391
Average scholarship amount	$17,111	---	---

Health Professions Institutional Assistance:
Authorizing Legislation - Sections 788B and 788(a) of the Public Health Service Act.

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Advanced Financial Distress	$4,100,000	$3,924,000	$3,924,000	---
Two-Year Medical and Osteopathy Schools	500,000	479,000	---	$-479,000
TOTAL	4,600,000	4,403,000	3,924,000	-479,000

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(b). Two-year medical and osteopathy schools	$500,000	$479,000	----	-$479,000

Purpose and Method of Operation

This program provides financial assistance to two-year basic science and/or clinical medical education programs to maintain and improve the quality of education programs in public and nonprofit schools which provide the first or last two years of education leading to the degree of doctor of medicine or osteopathy. These schools must be accredited by or be operated jointly with a school that is accredited by a recognized body or bodies approved for such purpose by the Secretary of Education. The use of these funds to support construction and the purchase of equipment is also authorized to schools which were in existence on September 30, 1985.

Rationale for the Proposed Rescission

A rescission of $479,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Impact Data

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Total Program Amount	$479,000	---	-$479,000
Total Number of Projects	2		-2

Health Promotion/Disease Prevention:
Authorizing Legislation - Sections 770(e), 791, 792, and 791A of the Public Health Service Act.

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Capitation	$5,000,000	$4,785,000	---	-$4,785,000
Graduate Programs in Health Administration	1,500,000	1,436,000	---	-1,436,000
Public Health Traineeships	3,000,000	2,871,000	---	-2,871,000
Health Administration Traineeships	500,000	479,000	---	-479,000
Preventive Medicine Residencies	1,600,000	1,531,000	---	-1,531,000
TOTAL	11,600,000	11,102,000	---	-11,102,000

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(c). Public health capitation...	$5,000,000	$4,785,000	---	-$4,785,000

Purpose and Method of Operation

Public Health Capitation grants provide Federal financial support to schools of public health to assist them in meeting the costs of their educational programs. Funds are awarded according to a formula established in the legislation; schools are required to maintain enrollment of full-time equivalent students enrolled in degree programs not less than such enrollment in school year 1983-84. Participating schools also are required to maintain the level of non-Federal expenditures existing in the previous year.

Rationale for the Proposed Rescission

A rescission of $4,785,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Impact Data

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Total Program Amount	$4,785,000	---	-$4,785,000
No. of P.H. Schools	23	---	-23
Estimated Enrollment Benefitted	7,300	---	-7,300
Average Amount per Student	$655	---	---

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(d). Graduate programs in health administration...	$1,500,000	$1,436,000	---	-$1,436,000

Purpose and Method of Operation

Grants are awarded to public or nonprofit private educational entities, including schools of social work but excluding schools of public health, in order to support the expansion and improvement of graduate programs, principally in health administration, hospital administration and health planning. To determine the amount of a grant award, the appropriation is divided by the number of approved applications from eligible schools. Eligible applicants are accredited health administration programs graduating at least twenty-five students a year, unless at least 45% of enrolled students are minorties in which case they may graduate twenty students a year. Eligible applicants also must expend at least $100,000 each year in funds from non-Federal sources to conduct the health administration program.

Rationale for the Proposed Rescission

A rescission of $1,436,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Impact Data

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Total Program Amount	$1,436,000	---	-$1,436,000
No. of Awards	30	---	-30
No. of Students Benefitted	2,250	---	-2,250

		1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(e).	Public health traineeships.	$3,000,000	$2,871,000	---	-$2,871,000

Purpose and Method of Operation

Grants are awarded to schools of public health and other public or non-profit institutions providing graduate or specialized training in public health. The traineeships awarded by the grantee provide financial support to students for tuition and living expenses. This program supports graduate or specified training in key public health fields, e.g., biostatistics, epidemiology, dietetics, nutrition, environmental health, occupational health, health administration, health planning, health policy analysis, preventive medicine or dentistry, and maternal and child health. The current law requires 65% of the funds be awarded to students with either a baccalaureate degree or three years work experience in health services. The student also must be pursuing a course of study in one of the above public health areas.

Rationale for the Proposed Rescission

A rescission of $2,871,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Impact Data

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Program Amount	$2,871,000	---	-$2,871,000
Schools of Public Health[1/]	23	---	-23
No. of Students Supported	1,444	---	-1,444
Average Amount per Trainee	$1,988	---	---

[1/] Awards are made to institutions on a formula basis.

Health Professions

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(f). Health administration traineeships...	$500,000	$479,000	---	-$479,000

Purpose and Method of Operation

Grants are awarded to public or nonprofit educational institutions, including graduate schools of social work (excluding schools of public health), to support traineeships for graduate study in accredited programs in health administration, hospital administration, or health policy analysis and planning. Programs receiving traineeship funds are located in a variety of graduate schools, including health sciences, business, and public administration. Traineeships awarded under these grants provide for stipends and other allowances. At least 80 percent of each grant must be awarded to students who have previously received a baccalaureate degree or have three years of work experience in health services.

Rationale for the Proposed Rescission

A rescission of $479,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Impact Data

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Total Program Amount	$479,000	---	-$479,000
No. of Awards	33	---	-33
No. of Trainees Supported	358	---	-358
Average Amount per Trainee	$1,333	---	---

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(g). Preventive medicine residencies	$1,600,000	$1,531,000	---	-$1,531,000

Purpose and Method of Operation

The Preventive Medicine Residencies program provides for increasing the national pool of health professionals with an expertise in preventive health care. The program, through grants or contracts to schools of medicine, osteopathy, and public health, supports the planning, development, and operation of physician residency training programs in preventive medicine. The program also allows financial assistance (traineeships and fellowships) to residents in such programs who plan to specialize in preventive medicine. Residency programs that provide training in general preventive medicine and preventive medicine-public health are currently receiving grant support.

Rationale for the Proposed Rescission

A rescission of $1,531,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Impact Data

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Program Amount	$1,531,000	---	-$1,531,000
No. of Residency Projects/Programs.	13	---	-13
No. of Residents Benefiting	148	---	-148

Primary Care:
Authorizing Legislation - Sections 780, 783, 784, and 786 of the Public Health Service Act.

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Family Medicine/General Dentistry Residencies and Training				
	$36,000,000	$34,452,000	$13,000,000	-$21,452,000
General Internal Medicine and Pediatrics				
	18,500,000	17,704,000	5,842,000	-11,862,000
Family Medicine Departments				
	7,000,000	6,699,000	---	-6,699,000
Physician Assistants				
	4,800,000	4,594,000	---	-4,594,000
TOTAL	66,300,000	63,449,000	18,842,000	-44,607,000

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(h). Family medicine/general dentistry residencies and training	$36,000,000	$34,452,000	$13,000,000	-$21,452,000

Purpose and Method of Operation

Family Medicine

The Family Medicine Residencies and Training program supports grants and contracts to hospitals, schools of medicine, osteopathy, and other public or private nonprofit entities to provide a combination of allopathic residencies, osteopathic internships, faculty development, and predoctoral training in family medicine. This program also provides financial assistance for trainees in such programs who plan to specialize in the practice of family medicine.

General Dentistry

The General Dentistry Residencies and Training program supports grants to accredited schools of dentistry or post graduate dental training institutions to provide for residency programs in the general practice of dentistry. Funds may also be used to provide financial assistance for trainees.

Since the start of program assistance in 1978, 97 dental general practice residency programs have either been planned, developed, expanded or strengthened with Federal assistance. Currently, 1,298 residents have been trained in the programs receiving support. This is approximately 18 percent of all dental general practice residents graduated since 1978.

Rationale for the Proposed Rescission

A rescission of $21,452,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. The revised estimate of $13 million will support 76 continuing graduate training grants, 32 continuing predoctoral grants, and 24 continuing general dentistry grants.

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(h). Family medicine/general dentistry residencies and training	$36,000,000	$34,452,000	$13,000,000	-$21,452,000

Purpose and Method of Operation

Family Medicine

The Family Medicine Residencies and Training program supports grants and contracts to hospitals, schools of medicine, osteopathy, and other public or private nonprofit entities to provide a combination of allopathic residencies, osteopathic internships, faculty development, and predoctoral training in family medicine. This program also provides financial assistance for trainees in such programs who plan to specialize in the practice of family medicine.

General Dentistry

The General Dentistry Residencies and Training program supports grants to accredited schools of dentistry or post graduate dental training institutions to provide for residency programs in the general practice of dentistry. Funds may also be used to provide financial assistance for trainees.

Since the start of program assistance in 1978, 97 dental general practice residency programs have either been planned, developed, expanded or strengthened with Federal assistance. Currently, 1,298 residents have been trained in the programs receiving support. This is approximately 18 percent of all dental general practice residents graduated since 1978.

Rationale for the Proposed Rescission

A rescission of $21,452,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. The revised estimate of $13 million will support 76 continuing graduate training grants, 32 continuing predoctoral grants, and 15 continuing general dentistry grants.

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(i). General internal medicine and pediatrics	$18,500,000	$17,704,000	$5,842,000	-$11,862,000

Purpose and Method of Operations

The General Internal Medicine and Pediatrics program, through grants and contracts to hospitals, schools of medicine, osteopathy, and other public or private nonprofit entities, supports projects to plan, develop, and operate approved residency programs in internal medicine or pediatrics. These Federal programs must emphasize ambulatory care, comprehensive health care and non-clinical areas relevant to the practitioner of general internal medicine and general pediatrics. The authority also provides financial assistance for faculty development and for traineeships and fellowships to residents who are participating in these programs, and who plan to practice general internal medicine or general pediatrics.

Rationale for the Proposed Rescission

A rescission of $11,862,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. The revised estimate of $5,842,000 will support 30 continuation grants.

In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Health Professions

2(1). General internal medicine and pediatrics

Impact Data

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Total Program Amount	$17,704,000	$5,842,000	$11,862,000
Total Number of Projects	96	30	-66
Graduate			
Program Amount	$16,804,000	$5,842,000	-$10,962,000
Number of Projects	87	30	- 57
Number of First-Year Positions Supported	597	195	-402
Number of Total Residents Assisted by this Budget	1,473	508	-965
Faculty Development			
Program Amount	$900,000	---	-$900,000
Number of Projects	9	---	-9
Number of Faculty Trained	81	---	-81

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(j). Family medicine departments	$7,000,000	$6,699,000	---	-$6,699,000

Purpose and Method of Operation

This program provides for grants to schools of allopathic and osteopathic medicine to establish, maintain, and/or improve academic administrative units to provide clinical instruction in family medicine. Units must be comparable to those for other major clinical specialties in status, faculty, and curriculum and must control a three-year family practice residency program or its equivalent.

Rationale for the Proposed Rescission

A rescission of $6,699,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Impact Data

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Program Amount	$6,699,000	---	-$6,699,000
Total Projects	67	---	-67
No. of New Projects	(46)	---	-(46)
No. of Continuation Projects	(21)	---	-(21)
No. of Indivs. Participating in Supported Programs	12,730	---	-12,730

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(k). Physician assistants	$4,800,000	$4,594,000	---	-$4,594,000

Purpose and Method of Operation

This activity supports projects to plan, develop, operate, or maintain primary care physician assistant training programs. Awards are made through grants or contracts to schools of medicine and osteopathy, and other public or nonprofit private entities. Programs supported are required to develop and use: (1) methods designed to encourage graduates of the program to work in health personnel shortage areas; and (2) methods for placing graduates in positions for which they have been trained. Preference is given to those programs providing substantial portions of their training opportunities in health personnel shortage areas, being established in a State which does not have such a program, and conducting a program and sharing resources in conjunction with the training of primary care physicians.

Since the establishment of the physician assistant academic program in 1966, the profession has grown to an estimated 18,700 as of October 1983. Physician assistants practice in 50 States and the District of Columbia. Federal support was the primary stimulus for this accomplishment. It is estimated that between FY 1972-1985, a total of 13,117 students have graduated from federally-funded programs. Studies have shown that 47 percent of physician assistants are in communities of less than 50,000 and that 66 percent of physician assistants practice in primary care settings of which one quarter are located in communities under 10,000 population.

Rationale for the Proposed Rescission

A rescission of $4,594,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Health Professions

2(k). Physician assistants

Impact Data

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Total Program Amount	$4,594,000	---	-$4,594,000
Number of Awards	44	---	-44
Number of PA Trainees	1,876	---	-1,876

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(1). Special educational initiatives...	$8,000,000	$7,656,000	---	-$7,656,000

Purpose and Method of Operation

The Health Professions Special Educational Initiatives program supports special high priority health professions projects of national importance. This program provides grant and contract support to health professions institutions, or other public or nonprofit private entities, for targeted health professions projects in a variety of priority areas. Students are trained to function effectively and efficiently as members of health care delivery teams and address both current and emerging health problems.

Geriatric/Long-Term Care

The Geriatric/Long-Term Care program supports the development of regional resource centers which strengthen the multidisciplinary training of primary care and other health professionals in geriatric health care. The regional resource centers train medical, osteopathic, dental, optometric, pharmacy, podiatric, nursing and relevant allied and public health faculty, students and practitioners in the diagnosis, treatment and prevention of diseases and related health care problems of the aged. In addition, they facilitate the training of health professions students and practitioners in other institutions.

Special Initiatives

This program addresses national problems in areas such as: (1) health promotion and disease prevention; (2) curriculum development in the organization, delivery and financing of health care; (3) economics in health professions practice and systems management; (4) clinical nutrition curriculum development; (5) competency assurance of health professionals; and (6) high priority health and health care delivery issues. The program also provides support to accredited podiatric medical schools to meet the cost to recruit students who reside in areas having shortages of podiatric personnel and to develop and operate clinical training programs in or near podiatric manpower shortage areas.

Health Professions

2(1). Special educational initiatives

Rationale for the Proposed Rescission

A rescission of $7,656,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of this decade.

Impact Data

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Total Program Amount:	$7,656,000	---	-$7,656,000
(Continuations)....	(6,400,000)[1]	---	(-6,400,000)
(New)..............	(1,256,000)	---	(-1,256,000)
Total Projects;	30	---	-30
(Continuations)....	(19)	---	(-19)
(New)..............	(11)	---	(-11)

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[1] Includes $1,000,000 to award three grants in Podiatry Specialty Training and $5,400,000 to award 16 Geriatric/Long-Term Care continuation projects.

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(m). Area health education centers	$18,000,000	$17,226,000	$4,743,000	-$12,483,000

Purpose and Method of Operation

The Area Health Education Centers (AHEC) program is designed to increase the number of health practitioners in shortage areas. This program provides funds to medical and osteopathic schools for the purposes of decentralizing education by having portions of training provided in primary medical personnel shortage areas and improving the coordination and use of existing health resources. The AHEC concept is a regionalized systems approach to the development of needed health personnel. In addition, Section 781(a)(2) authorizes Federal assistance to medical and osteopathic schools which have previously received Federal financial assistance for the AHEC program under either Section 802 of P.L. 94-484 in 1979 or under Section 781. This authority provides incentives to stimulate programs responsive to regional needs such as areas related to minority recruitment and training and to geriatrics.

The AHEC program requires that 10 percent of each medical school's undergraduate clinical education occur in an AHEC center. These centers are located away from the medical school campus. AHECs also provide primary care residency training and multidisciplinary training and practice involving physicians and other health personnel. Each project contains multiple centers at different stages of development. The law also requires that AHEC programs cost-share with the Federal Government a minimum of 25 percent of the program's total cost. Federal support spans approximately six years. Data indicate that AHECs generate a large measure of complementary support in the form of contributed faculty time for consultation services and provision of continuing education lectures, local physicians' teaching time, library resources, etc.

Health Professions

2(m). Area health education centers

Rationale for the Proposed Rescission

A rescission of $12,483,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending.

In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Impact Data

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Total Program Amount	$17,226,000	$4,743,000	-$12,483,000
New AHECs	(254,753)	(—)	(-254,753)
Continuation AHECs	(15,248,247)	(4,743,000)	(-10,505,247)
Special Initiatives	(1,723,000)	(—)	(-1,723,000)
Total Number of Projects	35	3	-32
New AHECS	(1)	(—)	(-1)
Continuation AHECs	(16)	(3)	(-13)
Special Initiatives	(18)	(—)	(-18)
Program Impact			
Students Trained	15,400	5,950	-9,450
Counties Served	169	108	-61
Regional Centers Supported	41	14	-27
States Participating	14	3	-11

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(n). Disadvantaged assistance	$25,500,000	$24,403,000	$13,000,000	$11,403,000

Purpose and Method of Operation

Health Careers Opportunity Program (HCOP)

The Health Careers Opportunity Program (HCOP) helps assure that opportunities for minority and disadvantaged individuals to obtain a health professions and allied health professions education are not inappropriately limited. This program is the principal Federal program directed at increasing the numbers of underrepresented minorities and other disadvantaged individuals who are interested in pursuing a health career. Funds are awarded through grants and contracts to public and non-profit private health or educational entities to support the identification, motivation, recruitment, admissions, retention, and placement of minority and disadvantaged students. Legislation stipulates that no less than 80 percent of the funds be awarded to institutions of higher education and not more than 5 percent of such funds be awarded to institutions having the primary purpose of informing individuals about the existence and general nature of health careers.

Stipends for Disadvantaged Students of Exceptional Financial Need

Authorizing legislation directs that, of the total funds appropriated for Disadvantaged Assistance, twenty percent will be made available for stipend support for disadvantaged students of exceptional financial need who are enrolled in a school of medicine, osteopathy, or dentistry.

Stipends up to $10,000 per student per year may be made available to minority and disadvantaged students with exceptional financial need enrolled in an eligible school of medicine, dentistry, or osteopathy. There is no obligatory service pay-back provision for students receiving these stipends. Recipients must meet part (a) of the Disadvantaged Background Definition cited in 42 CFR Part 57 of the Section 787 regulations, and the Exceptional Financial Need (EFN) eligibility criteria contained in Section 758 of the PHS Act. Eligible institutions must be a school of medicine, osteopathy, or dentistry (MOD) enrolling disadvantaged students of exceptional financial need.

Health Professions

2(n). Disadvantaged assistance

Rationale for the Proposed Rescission

A rescission of $11,403,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

The revised estimate of $13,000,000 has been earmarked to fund (100) HCOP continuation project grants. The new stipend program for HCOP Students of Exceptional Financial Need will not be implemented.

Impact Data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Health Careers Opportunity Program (HCOP)			
Total Program Amount	$ 19,523,000	$ 13,000,000	-$6,523,000
Continuation Amount	17,248,000	(13,000,000)	(- 4,248,000)
New Amount	2,275,000	(---)	(- 2,275,000)
Total No. of Projects	151	100	-51
Continuation Projects	(133)	(100)	(-33)
New Projects	(18)	(---)	(-18)
Students Benefitting	22,500	15,000	-7,500
Direct Benefitting	(9,000)	(6,000)	(-3,000)
Indirect Benefitting	(13,500)	(9,000)	(-4,500)
Stipends for Disadvantaged Students of EFN			
Program Amount	$ 4,880,000	---	-$4,880,000
No. of Recipients	488	---	-488
Average Stipend Amount	$ 10,000	---	---

Health Professions

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(o). Health professions analytical studies and reports.....	$2,000,000	$1,914,000	$1,500,000	- $414,000

Purpose and Method of Operation

The Health Professions Analytical Studies and Reports program provides up-to-date, carefully analyzed information on the supply, distribution and utilization of practicing health professionals and on health professions students and institutions. This information is used by the Department, the Congress, and the private sector in making national health policy decisions. The health fields encompass over 6 million workers and over 1,700 health professions schools enrolling almost 400,000 students.

The Public Health Service Act directs the Secretary of Health and Human Services to carry out a wide variety of data collection and analytical activities through this program. For example:

- The establishment of a data system to protect the public by assisting the Secretary of DHHS to identify and exclude from Medicare/Medicaid those physicians who have been disciplined by State Medical Boards;
- monitoring of the changes and trends of physicians and other health professionals and the cost of care they provide;
- analysis and interpretation of data on: health care financing and reimbursement; geographic location of practitioners; and relationships between physicians and nonphysician health care providers;
- the collection and projection of data on the enrollments and supply of minority persons in the health professions schools and in practice;
- preparation of reports to the President and Congress on the status of the health professions.

In addition, this program is charged with the responsibility for designating health manpower shortage areas (HMSAs) throughout the

United States in coordination with other federal programs, the States, local communities, and professional groups.

Rationale for the Proposed Rescission

A rescission of $414,000 is proposed as part of the President's overall budget reform to curtail Federal Government spending.

In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

The revised estimate of $1,500,000 supports 15 continuing contract activities.

Impact Data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Total Program	$1,914,000	$1,500,000	- $414,000
Continuing Activities	(1,914,000)	(1,500,000)	(- 414,000)
New Activities	(---)	(---)	(---)
Total Projects	19	15	- 4
Continuing Activities	(19)	(15)	(- 4)
New Activities	(---)	(---)	(---)
Program Activities			
Health Care Costs Containment	4	3	- 1
Health Promotion/Disease Prevention	3	3	---
Underserved Populations	4	4	---
Geriatrics and Long-term Care	3	1	- 2
Minorities/Disadvantaged	2	2	---
Access to Health Care	3	2	- 1

Nursing:
Authorizing legislation - Section 301, 487, 821, 820, 822, 830, and 837 and 831(b) (as amended by the Orphan Drug Act of the Public Health Service Act)

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Advance Nurse Education	$16,500,000	$15,790,000	$3,719,000	$-12,071,000
Nurse Practitioner/Nurse Midwife	12,000,000	11,484,000	378,000	-11,106,000
Nursing Special Projects	9,500,000	9,092,000	2,345,000	- 6,747,000
Professional Nurse Traineeships	11,500,000	11,005,000	---	-11,005,000
Nursing Research Fellowships	2,000,000	1,914,000	733,000	-1,181,000
Nursing Research Grants	9,700,000	9,283,000	1,493,000	-7,790,000
Nursing Student Loans	---	---	---	---
Nurse Anesthetists	800,000	766,000	---	- 766,000
Nurse Demonstration Projects	1,350,000	1,292,000	---	- 1,292,000
Nurse Faculty Fellowships	550,000	526,000	---	- 526,000
Center for Nursing Research [1/]	(5,000,000)	(5,000,000)	(---)	(-5,000,000)
TOTAL	63,900,000	61,152,000	8,668,000	-52,484,000

[1/] The FY 1985 Supplemental Act (P.L. 99-88) reappropriated $5,000,000 for the Center for Nursing Research extending the availability of funds through FY 1986. The unobligated balance of $5,000,000 is proposed for rescission in FY 1986.

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(p). Advanced nurse education..	$16,500,000	$15,790,000	$3,719,000	-$12,071,000

Purpose and Method of Operation

The Advanced Nurse Education program provides institutional support through grants or contracts to public and nonprofit private collegiate schools of nursing to meet the costs of projects to plan, develop, operate, expand, or maintain programs for the advanced training of professional nurses (master's and doctorate levels). Programs are funded which train nurses to serve as nurse educators, administrators, researchers or to serve in clinical nurse specialties determined by the Secretary to require advanced education.

Rationale for the Proposed Rescission

A rescission of $12,071,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. The revised estimate of $3,719,000 will support 21 continuing grants. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Impact Data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Total Program Amount	$15,790,000	$3,719,000	-$12,071,000
(Continuations)	(13,056,000)	(3,719,000)	(-$9,337,000)
(New)	(2,734,000)	(---)	(-$2,734,000)
Total No. of Projects	91	21	-70
(Continuations)	(76)	(21)	(-55)
(New)	(15)	(--)	(-15)
No. of Students Enrolled	2,000	481	-1,519

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(q). Nurse practitioner/ nurse midwife..	$12,000,000	$11,484,000	$378,000	-$11,106,000

Purpose and Method of Operation

The Nurse Practitioner and Nurse Midwife program provides grants or contracts to public or nonprofit schools of nursing, public health and medicine (which received a grant or contract under this subsection prior to October 1, 1985); public or nonprofit private hospitals; and other public or nonprofit entities to: plan, develop, operate, expand or maintain programs to educate nurse practitioners and nurse midwives. The focus of these programs is primary health care which includes: health promotion, disease prevention, basic care during acute and chronic phases of illness, guidance and counseling and referral to other health care providers when appropriate.

Rationale for the Proposed Rescission

A rescission of $11,106,000 is proposed as part of the President's overall budget reform plan to curtain Federal Government spending. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Impact Data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Total Program Amount	$11,484,000	$378,000	-$11,106,000
(Continuations)	(7,200,000)	(378,000)	(-6,822,000)
(New)	(4,284,000)	---	(-4,284,000)
Total No. of Projects	60	2	-58
(Continuations)	(39)	(2)	(-37)
(New)	(21)	(—)	(-21)

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(r). Nursing special projects......	$9,500,000	$9,092,000	$2,345,000	-$6,747,000

Purpose and Method of Operation

The nursing special project grant authority provides support to public and private entities to assist in efforts to meet the following priority areas: demonstrate improved geriatric training in preventive, acute and long term care; increasing nursing education opportunities for individuals from disadvantaged backgrounds; helping nurses to maintain existing skills and acquire new knowledge and skills through programs of continuing education; providing refresher training for nurses who wish to return to active practice; improve the supply and distribution of nurses in relation to geographic area and specialty distribution; provide career mobility for licensed practical nurses and paraprofessional nursing personnel.

Some of these projects assist in recruiting and retaining minorities and disadvantaged individuals in nursing; others support Departmental priorities such as improving care of the elderly and rectifying problems of geographic distribution.

Rationale for the Proposed Rescission:

A rescission of $6,747,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. The revised estimate of $2,345,000 supports 20 continuing grants. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Impact Data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Total Program Amt.	$9,092,000	$2,345,000	-$6,747,000
(Continuations)	(5,058,000)	(2,345,000)	(-2,713,000)
(New)	(4,034,000)	---	(-4,034,000)
Total No. of Projects	72	20	-52
(Continuations)	(40)	(20)	(-20)
(New)	(32)	(—)	(-32)

Health Professions

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(s). Professional nurse traineeships...	$11,500,000	$11,005,000	---	-$11,005,000

Purpose and Method of Operation

The Professional Nurse Traineeship program provides grants to eligible public or nonprofit institutions which in turn provide financial support through traineeships to registered nurses for full-time study in programs of advanced nurse education required for leadership positions as teachers, administrators/researchers, nurse practitioners/nurse midwives and clinical specialists. Special consideration is given to nurse practitioners to be nurse midwives.

Rationale for the Proposed Rescission

A rescission of $11,005,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Impact Data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Program Amount	$11,005,000	---	-$11,005,000
No. of Institutions	157	---	-157
No. of Trainees Supported	4,100	---	-4,100
Average Amt. per Trainee	$2,684	---	---

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(t). Nursing research fellowships....	$2,000,000	$1,914,000	$733,000	-$1,181,000

Purpose and Method of Operation

The Nursing Research Fellowship program provides grants to individuals and institutions in support of predoctoral and postdoctoral fellowships. These awards are made to (1) prepare professional nurses to conduct independent and interdisciplinary research to extend the scientific base of nursing practice, and (2) increase the number of nurses with research training in nursing or the basic sciences to serve as faculty in basic and advanced programs of nursing education. The period of award made may not exceed five years in the aggregate for predoctoral training and three years in the aggregate for postdoctoral training.

The Nursing Research Fellowship program is part of the nursing research and research training activities as reauthorized by the Health Research Extension Act of 1985, P. L. 99-158.

Rationale for the Proposed Rescission

A rescission of $1,181,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. The revised estimate of $733,000 will support 58 continuations and 12 new grants. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Impact Data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Total Program Amt.	$1,914,000	$733,000	-$1,181,000
Fellowships-Cont.	(1,400,616)	(606,376)	(-794,240)
Fellowships-New	(313,384)	(126,624)	(-186,760)
Institutional Grants	(200,000)	(---)	(-200,000)
Total No. of Projects	155	70	-85
Felllowships-Cont.	(124)	(58)	(-66)
Fellowships-New	(29)	(12)	(-17)
Institutional Grants	(2)	(--)	(-2)

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(u). Nursing research grants.......	$9,700,000	$9,283,000	$1,493,000	-$7,790,000

Purpose and Method of Operation

The Nursing Research Grants program provides grants and contracts to public and private organizations and institutions to support high quality research projects which relate to nursing practice, education, and delivery of services. Research projects focus on promoting health, well-being, and competency for personal care among all age groups; preventing health problems throughout the life span that have the potential to reduce productivity; decreasing the negative impact of health problems on coping abilities, productive life satisfaction of individuals and families; ensuring that the care needs of the particularly vulnerable are met through appropriate strategies; and designing and developing health care systems that are cost-effective in meeting the nursing needs of the population.

The Nursing Research Grants program is part of the nursing research and research training activities as reauthorized by the Health Research Extension Act of 1985, P.L. 99-158.

Rationale for the Proposed Rescission

A rescission of $7,790,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. The revised estimate of $1,493,000 will support 6 continuing and 1 new grant. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Impact Data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Total Program Amt.	$9,283,000	$1,493,000	-$7,790,000
(Continuations)	(6,933,000)	(1,341,098)	(-5,591,902)
(New)	(2,350,000)	(151,902)	(-2,198,098)
Total No. of Projects	80	7	-73
(Continuations)	(57)	(6)	(-51)
(New)	(23)	(1)	(-22)

Health Professions

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(v). Nurse anesthetist program.......	$800,000	$766,000	---	-$766,000

Purpose and Method of Operation

The Nurse Anesthetist program provides grants to public or nonprofit private institutions which in turn provide financial support through traineeships to registered nurses to become nurse anesthetists. The nurse anesthetist program requires full-time study and clinical practice of approximately 24 months to qualify the nurse for certification as a registered nurse anesthetist (CRNA).

Rationale for Proposed Rescission:

A rescission of $766,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Impact Data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Program Amount	$766,000	---	-$766,000
No.of Institutions	75	---	-75
No. of Trainees Supported	574	---	-574

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(w). Nurse demonstration projects........	$1,350,000	$1,292,000	---	$-1,292,000

Purpose and Method of Operation

The broad objective of the demonstration projects is to increase collaboration between nursing services and education. The authority provides support to public and private entities to: (1) demonstrate clinical nurse education programs which combine educational curricula and clinical practice in health care delivery organizations, including acute, long-term, and ambulatory care facilities; (2) improve access to nursing services in noninstitutional settings through support of nursing practice arrangements in communities; or (3) encourage nursing graduates to practice in health manpower shortage areas in order to improve specialty geographical distribution of nurses in the United States. This is a new program which was recently authorized by P.L. 99-92.

Rationale for the Proposed Rescission

A rescission of $1,292,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Impact Data	1986 after Sequestering	1986 Revised Estimate	Rescission
Program Amount	$1,292,000	---	-$1,292,000
No. of Projects	6	---	-6

Health Professions

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2(x). Nurse faculty fellowships....	$550,000	$526,000	---	-$526,000

Purpose and Method of Operation

The program authorizes funds to public or private nonprofit schools of nursing to cover the costs of post-baccalaureate fellowships for faculty to: investigate cost-effective alternatives to traditional health care modalities with special attention to the needs of at-risk populations; examine nursing interventions that result in positive outcomes in health status; and address other areas of nursing practice considered by the Secretary to require additional study. This is a new program recently authorized by P.L. 99-92.

Rationale for the Proposed Rescission

A rescission of $526,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Impact Data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Program amount	$526,000	---	-$526,000
Number of faculty assisted	526	---	-526

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
2(y). Center for nursing research 1/...	$5,000,000	$5,000,000	--	-$5,000,000

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[1] The FY 1985 Supplemental Act (P.L. 99-88) reappropriated $5,000,000 for the Center for Nursing Research, extending the availability of funds through FY 1986. The unobligated balance of $5,000,000 is proposed for rescission in FY 1986.

This program provides support for intramural and extramural activities of the Center for Nursing Research. The Center administers grant and contract projects and intramural activities related to nursing research and research training. The Center provides a focal point for promoting the growth and quality of research related to nursing and patient care and provides leadership to expand the pool of experienced nurse researchers.

The Center for Nursing Research is part of the nursing research and research training activities as reauthorized by the Health Research Extension Act of 1985, P.L. 99-158.

Rationale for Proposed Rescission

A rescission of $5,000,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. In view of projected national surpluses of health professionals by the end of this decade and their improving geographic distribution, continued Federal aid for the training of health professionals is no longer required. All major studies of supply and demand for health professionals conclude that virtually all occupations are in excess supply and that this will continue for the remainder of the decade.

Impact Data	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
Total Program Amount........	$5,000,000	--	-$5,000,000
Operational Activities.....	(3,000,000)	--	(-3,000,000)
Project Activities.........	(2,000,000)	--	(-2,000,000)
Total No. of Projects.......	17	--	-17

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
2(z). Health professions direct operations..	$20,200,000	$19,331,000	$15,040,000	-$4,291,000

Purpose and Method of Operation

Program support will provide funds to pay operating expenses associated with the administration of approximately 30 national health professions programs and activities, carrying out major debt management and student assistance activities, and performing close-out activities for health professions programs proposed for termination. Close-out expenses will include such costs as salaries; data processing costs; travel; supplies; equipment rental and purchase expenses; communications; printing; and postage.

Major debt management and student assistance activites include the administration of the Health Education Assistance Loan (HEAL) program, management of the Student Loan Insurance Fund, administration of the Health Professions and the Nursing Student Loan Revolving Fund programs. Specific annual program operations include, but are not limited to:

-- allocating insurance guarantees;
-- processing an estimated 30,000 HEAL applications and 2,000 HEAL preclaims requests;
-- communicating with public and other govermmental and Congressional offices, which includes approximately 40,000 responses;
-- conducting about 140 program reviews;
-- reviewing and analyzing approximately 6,300 quarterly debt management reports and monitoring delinquency standards of health professions and nursing schools;
-- reviewing and analyzing close to 1,400 accounts of HEAL defaulters;
-- implementing new requirements in the recently enacted nursing and health professions laws which include skip-tracing authority and credit collection activities, and referral of delinquent loans;
-- responding to requests for write-offs (eg. preparing legal summaries, etc.); and
-- preparing liability statements and handling extensive correspondence with students as more programs go into a closing status.

2(z). Health professions direct operations

Rationale for the Proposed Rescission

A rescission of $4,291,000 is proposed in Direct Operations for FY 1986 as part of the President's overall budget reform plan to curtail Federal Government spending.

The revised request of $15,040,000 will provide funds for operating expenses associated with administration of programs, debt management and collection activities, and close out activities.

Bureau of Health Maintenance Organizations and Resources Development

	1986 Appropriation	1986 Available after Sequestering	1986 Revised Estimate	Proposed Rescission
3(a). Local Planning	$15,680,000	$15,006,000	$3,440,000	-$11,566,000

Purpose and Method of Operation

This activity provides grants, based on a per capita formula, to local health planning bodies known as Health Systems Agencies (HSAs) which are predominately private non-profit organizations and are governed by boards representing cross sections of their communities with a majority of the members being consumers of health care services. These agencies perform a number of functions including data analyses leading to the development of long range health systems plans, the development of strategies for implementation of the plans, and making recommendations to the State Health Planning and Development Agencies on proposals for new institutional health services and facilities.

The were 141 agencies at the beginning of FY 1986, a decrease of one (1) from FY 1985. In addition, nine States and Territories receive local planning funds under Section 1536 of the PHS Act.

Rationale for the Proposed Rescission

A rescission of $11,566,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. The Administration believes that this program is inconsistent with the Administration's policy to eliminate Federal regulatory involvement in State and local health planning activities.

The Administration has opposed consistently the extension of the Federal health planning program as a barrier to entry for new, potentially more efficient health care providers. Activities supported by these grant funds have been largely concerned with procedural requirements in attempting to control the growth of health facilities and services. Moreover, with the reform of health care capital expenditures proposed for the Medicare program, the future need for a separate Federal health planning grant program is even less justifiable than in past years.

Bureau of Health Maintenance Organizations and Resources Development

	1986 Appropriation	1986 Available after Sequestering	1986 Revised Estimate	Proposed Rescission
3(b). State Planning	$4,800,000	$4,594,000	---	-$4,594,000

Purpose and Method of Operation

The program provides grants to State Health Planning and Development Agencies (SHPDAs) based on current census populations for the States. The primary responsibilities of SHPDAs are to (1) develop State health plans based on local health systems plans; (2) make decisions on proposals for new institutional health services and facilities; and (3) establish and maintain a State Health Coordinating Council (SHCC) whose members are appointed by the governors. There are 57 State Health Planning and Development Agencies.

Rationale for the Proposed Rescission

A rescission of $4,594,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government. The Administration continues to feel that this program is inconsistent with the Administration's policy to eliminate Federal regulatory involvement in State and local health planning activities.

The Administration has opposed consistently the extension of the Federal health planning program as a barrier to entry for new, potentially more efficient health care providers. Activities supported by these grant funds have been largely concerned with procedural requirements in attempting to control the growth of health facilities and services. Moreover, with the reform of health care capital expenditures proposed for the Medicare program, the future need for a separate Federal health planning grant program is even less justifiable than in past years.

Bureau of Health Maintenance Organizations and Resources Development

	1986 Appropriation	1986 Available after Sequestering	1986 Revised Estimate	Proposed Rescission
(3c). Planning Methods Development	$418,000	$400,000	---	-$400,000

Purpose and Method of Operation

Funds for this activity are used to provide technical assistance to and for planning agencies by three Centers for Health Planning. The Centers develop planning methods materials and hold workshops and training sessions for staff of the planning agencies. They focus a portion of their activity on consultations with agencies in solving problems of organization and planning strategies.

Rationale for Proposed Rescission

A rescission of $400,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. The Administration continues to feel that this program is inconsistent with the Administration's policy to eliminate Federal regulatory involvement in State and local health planning activities.

The Administration has opposed consistently the extension of the Federal health planning program as a barrier to entry for new, potentially more efficient health care providers. Activities supported by these grant funds have been largely concerned with procedural requirements in attempting to control the growth of health facilities and services. Moreover, with the reform of health care capital expenditures proposed for the Medicare program, the future need for a separate Federal health planning grant program is even less justifiable than in past years.

Bureau of Health Maintenance Organizations and Resources Development

	1986 Appropriation	1986 Available after Sequestering	1986 Revised Estimate	Proposed Rescission
(3d). Outpatient Medical Facility Construction	$5,000,000	$4,785,000	$750,000	-$4,035,000

Purpose and Method of Operation

This activity provides grants to public and non-profit private entities for construction or modernization of outpatient medical facilities which will provide services for medically underserved populations. The Department of Health and Human Services Appropriation Act, P.L. 99-178, provided $5,000,000 to be made available on a priority basis to facilities which have experienced a disruption in the availability of primary care services due to disasters such as hurricane, flood or fire.

Rationale for the Proposed Rescission

A rescission of $4,035,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government.

Bureau of Health Maintenance Organizations and Resources Development

	FY 1986 Appropriation	1986 Available after Sequestering	1986 Revised Estimate	Proposed Rescission
(3e).Direct Operations	$20,700,000	$19,810,000	$18,764,000	-$1,046,000

Purpose and Method of Operation: This activity provides salaries and expenses to support the personnel and management operations of Health Maintenance Organizations and Resources Development staff assigned to Central and Regional Offices.

Rationale for the Proposed Rescission

A rescission of $1,046,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending.

Health Resources and Services Administration

	1986 Appropriation Amount	1986 after Sequestering Amount	1986 Revised Estimate Amount	Rescission Amount
4. Office of the Administrator				
Total	$23,994,000	$22,962,000	$18,151,000	-$4,811,000
(a) Program Management	(15,994,000)	(15,306,000)	(14,111,000)	(-1,195,000)
(b) Facilities Planning and Engineering	(5,000,000)	(4,785,000)	(3,640,000)	(-1,145,000)
(c) Organ Transplant	(3,000,000)	(2,871,000)	(400,000)	(-2,471,000)

Purpose and Method of Operations - The Health Resources and Services Program Management activity is necessary to coordinate, direct, and manage the activities of the Health Resources and Services Administration. The Office of the Administrator supports a staff necessary to plan, direct, and administer the Bureau of Health Care Delivery and Assistance, the Bureau of Health Professions, the Bureau of Health Maintenance Organizations and Resources Development, and the Indian Health Service. This activity supports two broad functions - program planning and evaluation, and administrative management, which include direct staff assistance, policy guidance, management evaluations in the areas of contracts and grant administration, financial management, personnel management, property management, legislative services, communications and public affairs and equal employment opportunity. The Program Management activity also manages the Facilities Engineering functions which were transferred to the Health Resources and Services Administration in FY 1984 and the Organ Transplant activity authorized by the National Organ Transplant Act of 1984.

Rationale for Proposed Rescissions - A rescission of $4,811,000 is proposed as part of the President's overall budget reform plan.

The proposed funding level of $14,111,000 for the Office of the Administrator reflects the reduced level of program management required as a result of proposed rescissions in agency programs.

The amount of $3,640,000 for the Office of Engineering Services functions represents the level required to administer these activities now that the organization has been consolidated into three regional offices.

The $400,000 for Organ Transplant will allow the completion of developmental work on the operation of a national network to match donor organs with recipients.

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Bureau of Health Maintenance Organizations and Resources Development

HEALTH SYSTEMS AGENCY GRANT ALLOCATIONS

States	1986	FY 86 Revised	Proposed Rescission
TOTAL	$15,005,653 1/	$3,427,000 2/	$11,566,000
Alabama	---	---	---
Alaska	86,756	---	68,756
Arizona	241,157	---	241,157
Arkansas	451,966	383,604	68,362
California	685,422	211,845	473,577
Colorado	---	---	---
Connecticut	295,017	57,629	237,388
Delaware	35,443	---	35,443
Dist. of Col.	36,809	---	36,809
Florida	---	---	---
Georgia	442,998	15,526	427,472
Hawaii	58,957	---	58,957
Idaho	57,603	---	57,603
Illinois	758,646	65,967	692,679
Indiana	---	---	---
Iowa	266,294	---	266,294
Kansas	173,628	33,917	139,711
Kentucky	---	---	---
Louisiana	---	---	---
Maine	---	---	---
Maryland	411,289	61,846	349,443
Massachusetts	576,122	92,603	483,519
Michigan	911,452	---	911,452
Minnesota	220,171	---	220,171
Mississippi	100,576	---	100,576
Missouri	---	---	---
Montana	31,509	---	31,509
Nebraska	---	---	---
Nevada	52,769	---	52,769
New Hampshire	---	---	---
New Jersey	827,080	151,955	675,125
New Mexico	154,272	30,136	124 136
New York	1,805,957	265,931	1,540,026
North Carolina	448,576	19,330	429,246
North Dakota	88,769	11,539	77,230

Bureau of Health Maintenance Organizations and Resources Development

HEALTH SYSTEMS AGENCY GRANT ALLOCATIONS

States	1986	FY 86 Revised	Proposed Rescission
Ohio	1,700,147	1,442,996	257,151
Oklahoma	377,454	73,732	303,722
Oregon	166,331	---	166,331
Pennsylvania	1,042,760	428,358	614,402
Rhode Island	56,354	---	56,354
South Carolina	331,973	52,004	279,969
South Dakota	---	---	---
Tennesee	300,503	11,825	288,678
Texas	---	---	---
Utah	92,098	---	92,098
Vermont	30,656	---	30,656
Virginia	543,083	16,256	526,827
Washington	359,242	---	359,242
West Virginia	---	---	---
Wisconsin	312,237	---	312,237
Wyoming	---	---	---
American Samoa	29,697	---	29,697
Guam	29,697	---	29,697
Marianas	29,697	---	29,697
Puerto Rico	193,031	---	193,031
Trust Territory	29,697	---	29,697
Virgin Island	29,697	---	29,697
Evaluation set aside	150,056	---	137,057

1/ Reflects a reduction of $674,000 pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985, P.L. 99-177.

2/ Reflects a reduction of $13,000 pursuant to section 515 of the Treasury, Postal Service and General Government Appropriations Act of 1986 (PL 99-190).

Bureau of Health Maintenance Organizations and Resources Development

STATE HEALTH PLANNING AGENCY GRANT ALLOCATIONS

States	1986	FY 86 Revised	Proposed Rescission
TOTAL	$4,593,600 1/	---	$4,593,600
Alabama	59,070	---	59,070
Alaska	56,846	---	56,846
Arizona	56,846	---	56,846
Arkansas	56,846	---	56,846
California	56,846	---	56,846
Colorado	375,606	---	375,606
Connecticut	56,846	---	56,846
Delaware	56,846	---	56,846
Dist. of Col.	56,846	---	56,846
Florida	159,350	---	159,350
Georgia	85,524	---	85,524
Hawaii	56,846	---	56,846
Idaho	39,047	---	39,047
Illinois	171,375	---	171,375
Indiana	81,749	---	81,749
Iowa	56,846	---	56,846
Kansas	56,846	---	56,846
Kentucky	56,846	---	56,846
Louisiana	66,217	---	66,217
Maine	56,846	---	56,846
Maryland	64,217	---	64,217
Massachusetts	86,046	---	86,046
Michigan	135,313	---	135,313
Minnesota	61,830	---	61,830
Mississippi	56,846	---	56,846
Missouri	74,155	---	74,155
Montana	56,846	---	56,846
Nebraska	56,846	---	56,846
Nevada	56,846	---	56,846
New Hampshire	56,846	---	56,846
New Jersey	111,426	---	111,426
New Mexico	56,846	---	56,846
New York	263,598	---	263,598
North Carolina	90,746	---	90,746
North Dakota	56,846	---	56,846

Bureau of Health Maintenance Organizations and Resources Development

STATE HEALTH PLANNING AGENCY GRANT ALLOCATIONS

States	1986	FY 86 Revised	Proposed Rescission
Ohio	160,335	---	160,335
Oklahoma	56,846	---	56,846
Oregon	56,846	---	56,846
Pennsylvania	177,478	---	177,478
Rhode Island	56,846	---	56,846
South Carolina	56,846	---	56,846
South Dakota	56,846	---	56,846
Tennesee	69,902	---	69,902
Texas	234,608	---	234,608
Utah	56,846	---	56,846
Vermont	56,846	---	56,846
Virginia	82,808	---	82,808
Washington	64,158	---	64,158
West Virginia	56,846	---	56,846
Wisconsin	70,887	---	70,887
Wyoming	56,846	---	56,846
American Samoa	22,738	---	22,738
Guam	22,738	---	22,738
Marianas	22,738	---	22,738
Puerto Rico	56,846	---	56,846
Trust Territory	22,738	---	22,738
Virgin Island	22,738	---	22,738
Evaluation set aside	45,936		45,936

1/ Reflects a reduction of $206,400 pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985, P.L. 99-177.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR DISEASE CONTROL

Disease Control, Research, and Training

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR DISEASE CONTROL

Disease Control, Research, and Training

Appropriation Language

Of the funds made available under this head in Public Law 99-178, $34,096,000 are rescinded.

CENTERS FOR DISEASE CONTROL

11

Disease Control

Amounts Available for Obligation 1/

1986 Appropriation	$471,861,000 2/
1986 Sequester order	-20,290,000
Proposed rescission	-34,096,000
Subtotal, adjusted appropriation	417,475,000
Receipts and reimbursements from Non-federal sources:	
User fees	427,000
Unobligated balance, start of year	25,860,000
Unobligated balance, lapsing	-471,000
Total, obligations	443,291,000

1/ Excludes reimbursements of $[illegible].
2/ Includes $15,000,000 derived from unobligated balances provided under P.L. 94-266 for national influenza immunizations.

Summary of Changes

1986 Estimate..	$471,861,000
1986 Sequester order...	20,290,000
1986 Estimate after sequestering.................................	451,571,000
1986 Revised estimate..	417,475,000
Net change..	-34,096,000

	1986 base	Change from base
Decreases:		
Program:		
1. Prevention centers.................	$1,436,000	-$1,436,000
2. Infectious diseases		
AIDS -		
24-hour Hotline...........	1,914,000	-1,914,000
Alternate test sites......	9,934,000	-9,934,000
TB grants.........................	4,785,000	-4,785,000
3. Chronic and environmental disease prevention -		
Diabetes State projects........	4,785,000	-4,785,000
Designer drugs study...........	957,000	-957,000
4. Occupational safety and health -		
Training grants..................	8,383,000	-8,383,000
5. Buildings and facilities -		
Equipment for virology laboratory	1,902,000	-1,902,000
Total decreases................		-34,096,000
Net change.....................		-34,096,000

CENTERS FOR DISEASE CONTROL

Disease Control

Budget Authority by Activity

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	1986 Proposed Rescission
Prevention centers...........	$1,500,000	$1,436,000	-	-$1,436,000
Infectious diseases:				
Less AIDS..................	64,925,000	62,133,000	$50,285,000	-11,848,000
Infectious dis. comparable.	41,773,000	39,977,000	35,192,000	-4,785,000
Subtotal.................	106,698,000	102,110,000	85,477,000	-16,633,000
Chronic and environmental disease prevention..........	30,425,000	29,117,000	23,375,000	-5,742,000
Occupational safety and health:				
Research....................	58,923,000	56,389,000	56,389,000	-
Grants....................	6,501,000	6,221,000	6,221,000	-
Program operations.......	52,422,000	50,168,000	50,168,000	-
Training grants............	8,760,000	8,383,000	-	-8,383,000
Subtotal...............	67,683,000	64,772,000	56,389,000	-8,383,000
Buildings & facilities.......	3,797,000	3,634,000	1,732,000	-1,902,000
All other....................	261,758,000	250,502,000	250,502,000	-
Total......................	471,861,000	451,571,000	417,475,000	-34,096,000

Budget Authority by Object

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	1986 Proposed Rescission
Personnel compensation:				
Permanent positions............	$104,728,000	$100,225,000	$99,556,000	-$669,000
Positions other than permanent.	7,368,000	7,051,000	7,051,000	-
Other personnel compensation...	4,097,000	3,921,000	3,921,000	-
Subtotal, personnel comp......	116,193,000	111,197,000	110,528,000	-669,000
Personnel benefits...............	23,269,000	22,268,000	22,148,000	-120,000
Travel & transportation of persons	6,400,000	6,125,000	6,078,000	-47,000
Transportation of things..........	1,655,000	1,584,000	1,584,000	-
Rent, communications & utilities.	11,186,000	10,643,000	10,638,000	-5,000
Standard level user charges......	1,443,000	1,443,000	1,443,000	-
Printing and reproduction........	1,288,000	1,233,000	1,231,000	-2,000
Other services...................	16,694,000	15,976,000	15,926,000	-50,000
Project contracts..............	11,079,000	10,602,000	8,688,000	-1,914,000
Supplies and materials...........	33,217,000	31,789,000	31,787,000	-2,000
Equipment........................	15,477,000	14,811,000	12,909,000	-1,902,000
Lands and structures.............	701,000	671,000	671,000	-
Grants, subsidies & contributions	233,259,000	223,229,000	193,844,000	-29,385,000
Total, by object..............	471,861,000	451,571,000	417,475,000	-34,096,000

Centers for Disease Control

Disease Control

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
1. Prevention centers	$1,500,000	$1,436,000	---	$1,436,000

Purpose and Method of Operations

Prevention centers would be funded to conduct research and demonstration projects on health promotion and disease prevention techniques.

Rationale for the Proposed Rescission

A rescission of $1,436,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending.

Because of the overriding need for Federal fiscal constraint, it is difficult to justify starting new programs, such as prevention centers, at this time. CDC currently spends about $1 million a year on cooperative agreements and contracts for similar research and demonstration projects on health promotion and disease prevention. In addition, over $1.2 billion are spent each year by other Federal biomedical research agencies on prevention research activities.

Centers for Disease Control

Disease Control

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2. Infectious diseases:				
AIDS:				
Hot line..	$2,000,000	$1,914,000	---	-$1,914,000
Alternate test sites	$10,380,000	$9,934,000	---	-$9,934,000
TB grants..	$5,000,000	$4,785,000	---	-$4,785,000

AIDS Hotline

Purpose and Method of Operation

The Centers for Disease Control would establish, maintain, and operate under contract a 24-hour hotline which would permit calls to be made without charge to the caller, and would provide general information concerning Acquired Immune Deficiency Syndrome (AIDS) and information concerning medical services and housing facilities for individuals with such syndrome, and refer such individuals to counseling services.

Rationale for the Proposed Rescission

A rescission of $1,914,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending.

The Centers for Disease Control will continue to operate the national AIDS hotline that is now in existence, which provides updated AIDS information and referrals to local agencies and health departments for additional information and counseling. Many of the more affected communities (e.g., New York City, San Francisco, Chicago, Miami, New Orleans, Honolulu) are also supporting their own AIDS hotlines. Hotlines work best when they are affiliated with local service providers and can directly refer those in need to local service capacities. In addition, the Congress has provided over $20 million in 1986 to start risk reduction/health education programs in each of the States, which should result in more informed people and reduce the need to expand the current national AIDS hotline.

Alternate Sites

Purpose and Method of Operation

To protect the Nation's blood supply, funds for start-up of AIDS alternate test sites to blood donation stations were provided to States which applied. These resources were used by States to test persons for the presence of HTLV-III virus, the causative agent for AIDS in blood samples at sites other than blood donation stations.

Rationale for the Proposed Rescission

A rescission of $9,934,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending.

Funds provided in FY 1985 for the AIDS alternate test sites will not be continued. These funds were provided to State and local communities explicitly with the intent to cover start-up costs and accelerate the creation of alternative AIDS blood testing sites, after which the States and local communities were to continue ongoing support. CDC will continue its intensive efforts to develop new blood tests and continue to provide technical assistance to States and localities.

11.

Tuberculosis Grants

Purpose and Method of Operation

Provides grants to States and localities with relatively high-incidence of tuberculosis (TB) for implementation of TB control and prevention strategies. Funds are used primarily to hire outreach workers to enhance compliance with outpatient drug therapy among persons with TB.

Rationale for the Proposed Rescission

A rescission of $4,765,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending.

Alternative funds from the Preventive Health and Health Services Block Grants (funded at $87 million in 1986) and the Refugee Preventive Health Program (funded at $8 million in 1986) are available for this purpose. CDC will continue to provide consultation, training, disease surveillance, operational research, and other technical assistance to the States in TB control and prevention.

Centers for Disease Control

Disease Control

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
3. Chronic and environmental disease prevention:				
Diabetes State projects ...	$5,000,000	$4,785,000	---	$4,785,000
Designer drugs	$1,000,000	$957,000	---	$957,000

Diabetes State Projects

Purpose and Method of Operation

Since 1977, CDC has provided funds for State health departments to establish diabetes control programs. The purpose of the projects was to demonstrate that efforts to control and prevent complications resulting from the onset of diabetes could be cost-effective to the States. These programs have established organizational networks for translation, coordination, communications, and other capacity-building activities; conducted special studies to identify problems and factors contributing to excess diabetes morbidity; and implemented and evaluated interventions in a variety of community settings. Programmatic linkages between diabetes, hypertension, maternal and child health, and other chronic disease programs have been increased. Several project States have demonstrated that education programs lead to cost savings from decreased hospitalizations. Other non-project States have either started their own diabetes control programs or secured third-party reimbursement for patient education.

Rationale for the Proposed Rescission

A rescission of $4,785,000 and 20 FTE is proposed as part of the President's overall budget reform plan to curtail Federal Government spending.

A rescission is proposed to discontinue the State diabetes projects. Current State diabetes control projects have had Federal developmental support for 6 to 8 years ($5 million in 1985). Now these demonstration projects should be continued by the States or other third-party payment sources which have also benefitted financially from their success. Sufficient knowledge and experience is available, and States can use alternative funding sources to continue these activities. CDC will continue to provide technical assistance to States seeking to implement diabetes control programs.

Designer Drugs Study

Purpose and Method of Operation

Research would be conducted on the prevalence of designer or synthetic drug use and the clinical effects of these drugs over time. Scientists would follow the more than 400 young people who CDC has identified as having Parkinson type symptoms from a bad batch of these drugs and identify more such cases. Studies of users taking the fentanyl series of these drugs would also be initiated.

Rationale for the Proposed Rescission

A rescission of $477,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending. These funds were added to the budget by Congress in excess of the Administration's request and the program's needs. Determinations on the need for long-term epidemiological studies should be considered in the context of all other drug abuse research and should compete through the peer review process for available funds.

Centers for Disease Control

Disease Control

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
4. Occupational safety and health: Training ...	$8,760,000	$8,383,000	---	-$8,383,000

Purpose and Method of Operation

This program has provided limited Federal support to allow major universities that were institutionally committed to occupational training, to expand to meet increased student and employee interest in the occupational field.

The development of Occupational Safety and Health Educational Resource Centers (ERC) has demonstrated the effectiveness of providing both full time and continuing education--training occupational safety and health professionals, specialists, and technicians, as well as becoming a resource to management and labor for the region in which they are located.

Rationale for the Proposed Rescission

A rescission of $8,383,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending.

The Educational Resource Centers (ERC) have been federally funded for the past eight years. The proposed rescission represents the successful completion of the Federal ERC program of expanding university programs to meet increased student, business, and public health interest in the occupational health field, with a proposed shift toward State and private sector financing. The principal users of those individuals trained (industry and State governments) should now increase their financial support to maintain these centers. Nine of the existing 15 university-based ERC's have had Federal development support for eight years. They should now be able to sustain and continue their academic and continuing education training programs.

Centers for Disease Control

Disease Control

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
5. Buildings and facilities ..	$3,797,000	$3,634,000	$1,732,000	-$1,902,000

Purpose and Method of Operation

The CDC's Facility Planning Board has the responsibility to: (1) assess the adequacy of CDC facilities and equipment to do its job and to assure that all facilities, particularly laboratories, are safe for both workers and the community; (2) protect the facility investment of the Centers for Disease Control by preventing deterioration and by upgrading, where necessary, to ensure that facilities meet current required standards; and (3) meet the Centers' responsibility to reduce or conserve the energy necessary to operate the Centers' facilities and equipment.

To meet these goals, the Facility Planning Board continuously monitors the need for repair and improvement of the Centers' facilities. Priority rankings are assigned to each required project to ensure the accomplishment of those projects which are mandatory to protect the facility investment of the Centers and ensure that quality facilities are available to the programs of the Centers. The board also determines the need for equipment for new laboratories and other equipment.

Rationale for the Proposed Rescission

A rescission of $1,902,000 is proposed as part of the President's overall budget reform plan to curtail Federal government spending.

The proposed funding level will provide for the repairs and improvement projects necessary to protect CDC's facilities, but does not provide funds to purchase non-fixed scientific equipment for the virology laboratory now under construction. The laboratory will be equipped in phases.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Cancer Institute

FY 1986 Proposed Rescission

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NATIONAL INSTITUTES OF HEALTH

National Cancer Institute

Amounts Available for Obligation 1/

1986 Appropriation	$1,258,159,000
Enacted administrative reduction	-922,000
1986 Sequester order	-53,868,000
Proposed rescission	-6,800,000
Subtotal, adjusted appropriation	1,196,569,000
Real transfer to DHHS for Mary Babb Randolph Cancer Center	-4,500,000
Total, adjusted budget authority	1,192,069,000
Unobligated balance available start of year	6,714,000
Unobligated balance lapsing	-1,090,000
Total, obligations	$1,197,693,000

1/ Excludes the following amounts for reimbursable activities carried out by this account: 1986 - $1,000,000.

Summary of Changes

1986 Estimate	$1,259,451,000
Lapse	-1,090,000
1986 Sequester Order	-53,868,000
1986 Estimate After Sequester	1,204,493,000
1986 Revised Estimate	1,197,693,000
Net Change	$ -6,800,000

	1986 Base	Change from Base
Decreases		
Program		
1. Research Project Grants	$[illegible]	-6,800,000

NATIONAL INSTITUTES OF HEALTH

National Cancer Institute

Obligations by Activity

	1986 Appropriation 1/	1986 After Sequestering 1/2/	1986 Revised Estimate 1/2/	1986 Proposed Rescission
1. Cause & Prevention Research...	$ 317,957,000	$ 303,381,000	$ 301,381,000	-$2,000,000
2. Detection & Diagnosis Research....	82,767,000	80,095,000	79,595,000	-500,000
3. Treatment Research...............	396,237,000	377,775,000	375,375,000	-2,400,000
4. Cancer Biology Research......	260,638,000	250,033,000	248,133,000	-1,900,000
5. All Other...............	201,852,000	193,209,000	193,209,000	--
Total.............	$1,259,451,000	$1,204,493,000	$1,197,693,000	-$6,800,000

Obligations by Object

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	1986 Proposed Rescission
her Services..............	$ 436,186,000	$ 423,834,000	$ 423,834,000	--
Grants, Subsidies & Contributions..............	823,265,000	780,659,000	773,859,000	-$6,800,000
Total	$1,259,451,000	$1,204,493,000	$1,197,693,000	-$6,800,000

1/ All 1986 columns reflect an enacted administrative reduction of $922,000, a carryover in unobligated funds of $6,714,000, and a real transfer of $4,500,000 to the Department of Health and Human Services for the Mary Babb Randolph Cancer Center.

2/ Reflects a consultant services (Section 515 of the Treasury-Postal Service Appropriation Act, 1985) withholding of $1,090,000.

National Cancer Institute

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
1. Cause & Prevention Research...	$317,957,000	$303,381,000	$301,381,000	-$2,000,000

Purpose and Method of Operation

Cause and prevention research recognizes the interrelationships among factors which initiate and promote cancer including external influences, host factors, and the genetic endowment of the individual. Consequently it includes investigations into chemical and physical carcinogenesis, biological carcinogenesis, epidemiology, chemoprevention and nutrition. Each of these scientific areas interacts with the other: epidemiology attempts to identify environmental and genetic risk factors; chemical and physical carcinogenesis research seeks to elucidate the specific molecular ways in which chemical and physical agents trigger malignancy; biological carcinogenesis research, using viruses and defined DNA sequences as investigative tools, examines and analyzes the genes and gene products which can cause cancer; chemoprevention research aims to identify chemicals and other agents capable of preventing or reversing the process of carcinogenesis at one or more stages; and nutrition research attempts to identify foods, nutritional factors, and dietary habits that may either induce, promote or inhibit cancer. Research findings in any one of these areas may shed light on a problem being investigated in another, for ultimately each discipline is concerned with the fundamental causes and prevention of human cancer.

Rationale for the Proposed Rescission

The rescission of research project grant funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed funding level of $179,078,000 and 992 research project grants is a decrease of $2,000,000 and 30 grants from the sequestration level.

National Cancer Institute

Impact Data

1. Cause & Prevention Research	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
Mechanism			
Research Projects:			
Number	1,022	992	-30
Amount	$181,078,000	$179,078,000	-$2,000,000
Other Research Related			
Number	10	10	--
Amount	1,343,000	1,343,000	--
Total, Research Grants			
Number	1,032	1,002	-30
Amount	182,421,000	180,421,000	-2,000,000
Research & Development Contracts			
Number	175	175	--
Amount	58,446,000	58,446,000	--
Intramural Research	45,938,000	45,938,000	--
Research Management & Support	16,576,000	16,576,000	--
Total			
Number	1,207	1,177	-30
Amount	$303,381,000	$301,381,000	-$2,000,000

National Cancer Institute

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
2. Detection & Diagnosis Research.....	$82,767,000	$80,095,000	$79,595,000	-$500,000

Purpose and Method of Operation

Research on detection and diagnosis is directed toward improving the ability; 1) to identify populations and individuals at high risk; 2) to detect cancer at earlier stages and to detect precancerous abnormalities; 3) to characterize different tumor types, determine the stage of development and the prognosis; and 4) to monitor more effectively the changes during and following therapy. Identification of populations at high risk will result in appropriately targeted and more effective screening programs; development of new and better tests for detection will result in the ability to detect tumors before they become invasive or metastatic. Better classification schemes will provide more information concerning diagnosis and prognosis. Improvements in detection and diagnosis are critical to the physician's choice of the most effective therapeutic approach to decrease mortality from cancer and to improve survival rates.

Rationale for the Proposed Rescission

The rescission of research project grant funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed funding level of $41,790,000 and 274 research project grants is a decrease of three grants and $500,000 from the sequestration level.

National Cancer Institute

Impact Data

2. Detection & Diagnosis Research	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
Mechanism			
Research Projects:			
Number	277	274	-3
Amount	$42,290,000	$41,790,000	-$500,000
Other Research Related			
Number	3	3	--
Amount	19,000	19,000	--
Total, Research Grants			
Number	280	277	-3
Amount	42,309,000	41,809,000	-500,000
Research & Development Contracts			
Number	57	57	--
Amount	17,828,000	17,828,000	--
Intramural Research	15,917,000	15,917,000	--
Research Management & Support	4,041,000	4,041,000	--
Total			
Number	337	334	-3
Amount	$80,095,000	$79,595,000	-$500,000

National Cancer Institute

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
3. Treatment Research..............	$396,237,0	$377,775,000	$375,375,000	-$2,400,000

Purpose and Method of Operation

The past 30 years have witnessed a significant improvement in the effectiveness of treatments available to patients with cancer. The introduction of chemotherapy and its successful use in leukemia, lymphoma, and other solid tumors in the past two decades has now been followed by the identification of an entirely new form of therapy, the use of adoptive immunotherapy with white blood cells conditioned with the immune stimulant, Interleukin-2. The Institute's drug development program consists of two arms, a preclinical component designed to discover and develop new agents from among the many synthetic and naturally-occurring chemicals available in industry and academia, and secondly a clinical trials component designed to test the best of these candidate drugs in man and to identify their activity against specific types of human cancer.

Basic similarities have been discovered between the process that leads to tumor formation by carcinogens (carcinogenesis), and the process of drug resistance. For example, the newly discovered enzyme which attaches phosphate groups to regulatory molecules on the cell surface, known as protein kinase C, is markedly increased in activity during both processes. This fundamental link between carcinogenesis and drug resistance may explain the unique ability of tumor cells to escape drug toxicity, and suggests an important new target for antitumor drug design, the protein kinase C and its related phosphoinositol cycle.

In addition to the progress in understanding the reasons for drug resistance, major advances have been made in 1985 in the development of entirely new approaches to cancer treatment. These approaches are based on the knowledge and tools of modern molecular biology, immunology, and genetics; these disciplines have provided new targets for cancer treatment. Progress in understanding the basic properties of the malignant cell has led to appreciation that the cancer cell is dependent on unique growth factors, has specific surface proteins, and can be recognized and destroyed by special types of cells, called "killer cells", found in the immune system. The specific chemical processes that allow the cancer cell to invade neighboring tissue and to spread to distant parts of the body have been clarified and, in turn, have suggested new therapeutic approaches. All of these biological properties have become the subject of the Biological Response Modifiers Program, the newest treatment research program of the NCI. This program, established in 1980, is now paying its first dividends in terms of the highly effective treatment of hairy-cell leukemia with alpha interferon, and the important demonstration this year that patients with advanced tumors of the colon and kidney and with malignant melanoma (a highly lethal form of skin cancer) respond to a new form of immunotherapy.

Rationale for the Proposed Rescission

The rescission of research project grant funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed funding level of $166,164,000 and 758 research project grants is a decrease of $2,400,000 and 21 grants from the sequestration level.

National Cancer Institute

Impact Data

3. Treatment Research	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
Mechanism			
Research Projects			
Number	779	758	-21
Amount	$168,564,000	$166,164,000	-$2,400,000
Cooperative Clinical Research			
Number	228	228	--
Amount	48,045,000	48,045,000	--
Other Research Related			
Number	21	21	--
Amount	2,008,000	2,008,000	--
Total, Research Grants			
Number	1,028	1,007	-21
Amount	218,617,000	216,217,000	-2,400,000
Research & Development Contracts			
Number	205	205	--
Amount	63,993,000	63,993,000	--
Intramural Research	75,862,000	75,862,000	--
Research Management & Support	19,303,000	19,303,000	--
Total			
Number	1,233	1,212	-21
Amount	$377,775,000	$375,375,000	-$2,400,000

National Cancer Institute

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
4. Cancer Biology Research......	$260,638,000	$250,033,000	$248,133,000	-$1,900,000

Purpose and Method of Operation

Cancer biology research covers a broad spectrum of basic biological research in two major areas. One, tumor biology, advances our knowledge of the cellular and molecular factors which distinguish cancer cells from normal healthy cells and tissues. The other, immunology, focuses on determining the role of the immune system in controlling the development, growth and spread of tumors. Knowledge of these properties, processes and interactions are helping us learn how to prevent and counteract the biological signals responsible for the aberrant behavior of cancer cells. The most significant feature of basic cancer research is the emergence of unifying biological concepts from what once were considered diverse, unrelated areas of investigation. These unifying concepts bring together the most complex models for control of gene expression and cellular behavior, offering continued new opportunities and approaches for improving cancer prevention, diagnosis, treatment and the management of cancer patients. Basic research is rapidly providing improved tools for cancer diagnosis and prognosis and, more importantly, is setting the groundwork for the kinds of biological therapies which will markedly improve the effectiveness of cancer treatment.

Rationale for the Proposed Rescission

The rescission of research project grant funds is a necessary transition to the spending levels in the President's FY 1987 Budget.

The proposed funding level of [illegible] and [illegible] research project grants is a decrease of $1,900,000 and 15 grants from the sequestration level.

National Cancer Institute

Impact Data

4. Cancer Biology Research	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
Mechanism			
Research Projects:			
Number	1,004	974	-30
Amount	$172,036,000	$170,136,000	-$1,900,000
Other Research Related			
Number	51	51	--
Amount	5,758,000	5,758,000	--
Total, Research Grants			
Number	1,055	1,025	-30
Amount	177,794,000	175,894,000	-1,900,000
Research & Development Contracts			
Number	18	18	--
Amount	5,911,000	5,911,000	--
Intramural Research	56,609,000	56,609,000	--
Research Management & Support	9,719,000	9,719,000	--
Total			
Number	1,073	1,043	-30
Amount	$250,033,000	$248,133,000	-$1,900,000

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTE OF HEALTH

National Heart, Lung, and Blood Institute

FY 1985 Proposed Rescission

Page No.

Appropriation Language.. [illegible]

Amounts available for obligation.. [illegible]

Obligations by activity.. [illegible]

Obligations by object.. [illegible]

Justification

A. Heart and vascular diseases program.. [illegible]
B. Lung diseases.. [illegible]
C. Blood diseases program.. [illegible]

NATIONAL INSTITUTE OF HEALTH

National Heart, Lung, and Blood Institute

Of the funds made available under this head in Public Law 99-178, $11,469,000 are rescinded.

National Heart, Lung, and Blood Institute

Amounts Available for Obligation [1/]

1986 Appropriation..	$859,572,000
1986 Enacted administrative reduction..........................	-333,000
1986 Sequester order..	-36,947,000
Proposed rescission...	-11,469,000
Subtotal, adjusted appropriation............................	810,823,000
Unobligated balance, start of year..............................	639,000
Unobligatd balance lapsing......................................	-669,000
Total obligations...	810,793,000

[1/] Excludes [illegible] for reimbursable activities carried out by this account.

Summary of Changes

1986 Estimate..	$859,572,000
1986 Enacted administrative reduction..........................	-333,000
1986 Sequester order..	-36,947,000
1986 Estimate after sequestration...............................	822,292,000
1986 Revised Estimate...	810,823,000
	-11,469,000

	1986 Base	Change from Base
Decreases:		
Program:		
1. Research project grants..............	[illegible]	-11,469,000

National Heart, Lung, and Blood Institute

Obligations by Activity

	1986 1/ Appropriation	1986 After 1/2/ Sequestering	1986 Revised 1/2/ Estimate	1986 Proposed Rescission
1. Heart and vascular diseases program	$493,736,000	$472,523,000	$465,069,000	-$7,454,000
2. Lung diseases	136,727,000	130,852,000	128,788,000	-2,064,000
3. Blood diseases program	129,131,000	123,584,000	121,633,000	-1,951,000
4. All Other	100,284,000	95,303,000	95,303,000	---
Total	859,878,000	822,262,000	810,793,000	-11,469,000

Obligations by Object

	1986 1/ Appropriation	1986 After 1/2/ Sequestering	1986 Revised 1/2/ Estimate	1986 Proposed Rescission
Grants, subsidies, and, contributions	$700,549,000	$670,453,000	$658,984,000	-$11,469,000
Other services	159,329,000	151,809,000	151,809,000	---
Total, by object	859,878,000	822,262,000	810,793,000	-11,469,000

1/ Reflects an enacted administrative reduction of $333,000 and a carryover in unobligated funds of $639,000.

2/ Reflects a consultant services (Section 515 of the Treasury-Postal Service Appropriation Act, 1985) withholding of $669,000.

National Heart, Lung, and Blood Institute

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
1. Heart and vascular disease program.....	$493,736,000	$472,523,000	$465,069,000	-$7,454,000

Purpose and Method of Operations

Despite significant reductions in death rates over the past 21 years, cardiovascular diseases continue to rank high among the leading causes of death in the United States. The 978,000 deaths due to cardiovascular diseases in 1984 constituted nearly half of all deaths. According to data on the prevalence of heart and vascular diseases in the United States, more than 60 million persons have been diagnosed by their physicians as having hypertension, heart disease, or a circulatory disease.

The total annual cost associated with cardivascular diseases was estimated at $94 billion in 1982, by far the largest total for any diagnostic group of diseases. The direct costs alone (hospital care, physician and other professional services, drugs, and nursing home care) amounted to $41 billion, or 1 percent of the GNP. An additional $53 billion was lost to the economy in indirect costs (lost productivity and premature deaths).

To reduce the economic burden and the mortality and morbidity imposed on the Nation by cardiovascular disease, the Heart and Vascular Diseases Program will continue its emphasis on basic biomedical research, clinical applications of research, clinical trials, and prevention, education, and control programs. Ten program areas are emphasized, each representing a National Program category: arteriosclerosis, hypertension, cerebrovascular disease, coronary heart disease, peripheral vascular disease, arrhythmias, heart failure and shock, congenital and rheumatic heart disease, cardiomyopathies and infections of the heart, and circulatory assistance. Within these ten areas, major emphasis is focused on arteriosclerosis, hypertension, and coronary heart disease programs.

Rationale for the Proposed Rescission

A rescission of $7,454,000 is proposed for the Heart and Vascular Diseases Program. The rescission of research project grant funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed funding level of $465,069,000 will provide $337,619,000 for 1665 research project grants, a reduction of 46 competing projects and $7,454,000 from the amount available after sequestering.

1. Heart and vascular diseases program

Impact Data

	1986 Available after Sequestering	1986 Revised Estimate	Proposed Rescission
Research Project Grants			
Number.............	1,709	1,665	-44
Amount............	$345,064,000	$337,610,000	-$7,454,000

National Heart, Lung, and Blood Institute

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
2. Lung diseases program...............	$136,727,000	$130,852,000	$128,788,000	-$2,064,000

Purpose and Method of Operations

Respiratory diseases are among the leading causes of death and disability in the United States. About one in every five persons in this country reports some chronic respiratory problem, and chronic obstructive lung diseases are the fastest rising among the leading causes of death.

Pulmonary diseases have cost our Nation greatly both in human suffering and in dollars. Although many of these disease, once they occur, are chronic and incurable, many are preventable. Improved prevention and management of chronic pulmonary diseases provide a difficult and exciting challenge.

The broad mission of the Lung Diseases Program is to provide more effective diagnosis, treatment, and prevention of pulmonary diseases. A multifaceted approach is taken through improved understanding of the causes of disease, greater knowledge of pathogenesis, and improved techniques for early diagnosis and more effective management. To these ends, seven program areas are emphasized, each representing a National Plan category: structure and function of the lung (including lung development); chronic obstructive pulmonary diseases (emphysema, chronic bronchitis, and asthma); pediatric pulmonary diseases (neonatal respiratory distress syndrome, bronchopulmonary dysplasia, cystic fibrosis, and bronchiolitis); occupational and immunologic lung diseases; pulmonary vascular diseases (pulmonary hypertension and thromboembolism, and edema); respiratory failure; and prevention, control, and education.

Rationale for the Proposed Rescission

A rescission of $2,064,000 is proposed for the Lung Diseases Program. The rescission of research project grant funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed funding level of $128,788,000 will provide $85,416,000 for 514 research project grants, a reduction of 13 competing projects and $2,064,000 from the amount available after sequestering.

2. Lung diseases program

Impact Data

	1986 Available after Sequestering	1986 Revised Estimate	Proposed Rescission
Research Project Grants			
Number......................	527	514	-13
Amount......................	$87,480,000	$85,416,000	-$2,064,000

National Heart, Lung, and Blood Institute

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
3. Blood diseases and resources......	$129,131,000	$123,584,000	$121,633,000	-$1,951,000

Purpose and Method of Operations

For decades, the illnesses, deaths, and health care costs resulting from blood disorders were incompletely reported, and the quantities and costs of blood collected, processed, and transfused were not reported at all. Recent findings have revealed the widespread involvement of blood disorders in death and disability -- for example, the role of thrombosis in the pathology of many disorders.

In 1982, blood diseases were reported as the primary underlying cause of 329,000 deaths in the United States. More recently, in 1983, blood diseases were the primary reason for 6.7 million patient visits to physicians' offices and 17.5 million days of hospital care. In 1982, the estimated economic costs (expenditures for hospital care, professional services, nursing home care, drugs, and medical sundries, productivity lost through illness or death) amounted to $29.9 billion.

The NHLBI Blood Diseases and Resources Program is organized into four major categories: thrombosis and hemostasis, which include thromboembolic, platelet, and hemorrhagic disorders; red blood cell disorders, which include the thalassemias and aplastic anemia; sickle cell disease, which includes sickle cell diseases and variants and sickle cell trait; and blood resources, which includes blood component and derivative therapy, safety of blood therapy, immunohematology, blood substitutes, and blood resource management. In these areas, the Institute's mission is the support of research designed to reduce the morbidity caused by blood diseases, to lead to the primary prevention of these diseases, and to ensure the availability of adequate supplies of safe and effective blood products.

Rationale for the Proposed Rescission

A rescission of $1,951,000 is proposed for the Blood Diseases and Resources Program. The rescission of research project grant funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed funding level of $121,633,000 will provide $76,716,000 for 460 noncompeting and competing research project grants, a reduction of 13 competing projects and $1,951,000 from the amount available after sequestering.

3. Blood Diseases and Resources Program

Impact Data

	1986 Available after Sequestration	1986 Revised Estimate	Proposed Rescission
Research Project Grants			
Number..............	[illegible]	[illegible]	-12
Amount..............	[illegible]	[illegible]	-$1,951,000

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTE OF HEALTH

National Institute of Arthritis, Diabetes, and Digestive and Kindey Diseases

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NATIONAL INSTITUTE OF HEALTH

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

Of the funds made available under this head in Public Law 99-178, $7,980,000 are rescinded.

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

Amounts Available for Obligation

1986 Appropriation	$569,597,000
Enacted Administrative Reduction	-257,000
1986 Sequester Order	-24,482,000
Proposed rescission	-7,980,000
Subtotal, adjusted appropriation	536,878,000
Unobligated balance, start of year	3,213,000
Unobligated balance, lapsing	-616,000
Total, obligations	539,475,000

Summary of Changes

1986 Estimate	$571,937,000
1986 Sequester order	-24,482,000
1986 Estimate after sequestering	547,455,000
1986 Revised estimate	539,475,000
Net change	-7,980,000

	1986 Base	Change from Base
Decreases:		
Program:		
1. Research project grants	$386,327,000	-$7,980,000

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

Obligations by Activity

	1986 1/ Appropriation	1986 After 1/2/ Sequestering	1986 Revised 1/2/ Estimate	1986 Proposed Rescission
1. Arthritis, Musculoskeletal and Skin Diseases......	$107,895,000	$103,078,000	$101,554,000	-$1,524,000
2. Diabetes, Endocrinology and Metabolism....	203,217,000	194,320,000	191,014,000	-3,306,000
3. Digestive Diseases and Nutrition.....	91,238,000	87,243,000	85,798,000	-1,445,000
4. Kidney, Urology and Hematology....	95,249,000	91,083,000	89,378,000	-1,705,000
5. All Other.......	74,954,000	71,731,000	71,731,000	---
Total.........	572,553,000	547,455,000	539,475,000	-7,980,000

Obligations by Object

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	1986 Proposed Rescission
Other Services......	$87,625,000	$83,045,000	$83,045,000	---
Grants, Subsidies and Contributions.	484,928,000	464,410,000	456,430,000	-$7,980,000
Total...........	572,553,000	547,455,000	539,475,000	-7,980,000

1/ Reflects an enacted administrative reduction of $257,000 and a carryover in unobligated funds of $3,213,000.

2/ Reflects a consultant services (Section 515 of the Treasury-Postal Service Appropriation Act, 1985) withholding of $616,000.

National Institute of Arthritis, and Diabetes, and Digestive and Kidney Diseases

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	1986 Proposed Rescission
1. Arthritis, Musculoskeletal and Skin Diseases......	$116,498,000	$111,312,000	$109,788,000	-$1,524,000

Purpose and Method of Operation

Basic, developmental, and applied research is fostered in three major program areas in this Institute through the use of investigator-initiated research grants, research career development awards, center grant awards, intramural research programs, and research and development contracts. National Research Service Awards support the training of individuals for full-time academic careers in research and teaching.

Arthritis and Related Diseases

Arthritis and other rheumatic diseases afflict over 36 million Americans. Among the more than 100 kinds of arthritis and related disorders are such diseases as rheumatoid arthritis, osteoarthritis, juvenile arthritis, systemic lupus erythematosus, gout, spondylitis, and many inherited and acquired connective tissue disorders, such as scleroderma. Arthritis is the nation's primary crippler, causing increasing numbers of persons to leave work before normal retirement age. The resultant loss of earnings has been estimated at $25 billion a year. Arthritis is reported to affect more than 40 percent of people over age 65. In addition, an estimated 250,000 children have arthritis or a related joint disease. Some 100,000 of these children will carry serious handicaps into adulthood. In addition to disability, some forms of juvenile arthritis can cause kidney disease, blindness, and even premature death. NIAMS research is organized to be responsive to these public health needs and comprises a broad spectrum of fundamental research on causes of the diseases, complemented by clinical research on the treatment and possible prevention of specific rheumatic diseases.

Musculoskeletal Diseases

Orthopaedics research supported by the NIAMS encompasses both fundamental and clinical studies of bone and cartilage and other supporting structures in normal and disease states. The scope of this research includes basic biology of bone and cartilage; metabolic bone diseases; fractures and the healing process; prostheses and relevant biomaterials; biomechanics and bioelectric phenomena; bone transplantation; the physiology of normal and abnormal gait; and inherited connective tissue diseases.

Skin Diseases

Diseases of the skin reach a high toll in terms of disfigurement, discomfort, disability, and even death. Investigations are under way on a wide range of dermatological problems including psoriasis, vitiligo, acne, atopic dermatitis, lupus erythematosus, scleroderma, and potentially fatal "bullous" diseases such as pemphigus and epidermolysis bullosa. Employing sophisticated new laboratory techniques, scientists are working to clarify the roles of immune-mediated responses, phototoxicity, and metabolic derangements as causes of these disorders. Special emphasis will be given to applying monoclonal antibodies, gene cloning, and related techniques to basic research on macromolecular components of the skin in health and disease. This research will enable delineation of control mechanisms whereby hormones, enzymes, and specific minerals affect normal skin and cutaneous diseases, and will lead to eventual improvement in the care of patients with skin diseases.

Rationale for the Proposed Rescission

The rescission of research project funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed funding level of $109,788,000 will provide $78,506,000 for the research project grant mechanism. This will provide for the support of 173 competing research project grants, a decrease of 26 from those fundable under the 1986 level after sequestering. The total number of research project grants to be supported will be 556 within the rescission level.

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	1986 Proposed Rescission
2. Diabetes, Endocrinology and Metabolism...	$203,217,000	$194,320,000	$191,014,000	-$3,306,000

Purpose and Method of Operation

The NIDDK is a leader in basic and clinical research efforts on various serious diseases caused by errors of metabolism and defects in endocrine systems. These include diabetes, cystic fibrosis, thyroid diseases, and growth and reproductive disorders. In addition, NIDDK grantees have contributed valuable insights and knowledge regarding the metabolic and endocrine components of other diseases that affect the cardiovascular, musculoskeletal, and digestive systems. Research in these areas has progressed significantly during the past several years, in part as the result of recent advances in the application of genetic and immunologic techniques to the study of diabetes and endocrinologic and metabolic diseases.

Rationale for the Proposed Rescission

The rescission of research project funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed funding level of $191,014,000 will provide $153,202,000 for the research project grant mechanism. This will constitute a decrease of 37 from those fundable under the 1986 level after sequestering. The total number of research project grants to be supported will be 1,007 within the rescission level.

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

2. Diabetes, Endocrinology and Metabolism

Impact Data

	1986 After Sequestering	1986 Revised Estimate	1987 Estimate
Research Project Grants			
Number......................	1,044	1,007	-37
Amount......................	$156,508,000	$153,202,000	-$3,306,000

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	1986 Proposed Rescission
3. Digestive Diseases and Nutrition....	$91,238,000	$87,243,000	$85,798,000	-$1,445,000

Purpose and Method of Operation

Digestive diseases are a major cause of disability due to illness in the United States. These diseases encompass disorders of the salivary glands, esophagus, stomach, liver, gallbladder, biliary tract, pancreas, small and large intestines, and anorectum. Nutrition is a vital area of investigation due to the significant role that diet and nutritional factors have in health promotion and disease prevention. The interrelationship of digestive diseases and nutrition is evidenced in many ways: nutritional factors may initiate or aggravate a digestive disease, digestive diseases may lead to nutritional deficiences, and nutritional therapy may be used to combat or prevent a digestive problem. Basic and clinical research on digestive diseases and nutrition, supported by NIDDK, have advanced knowledge of the normal and disease states relevant to these research areas.

Rationale for the Proposed Rescission

The rescission of research project funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed funding level of $85,798,000 will provide $67,268,000 for the research project grant mechanism. This will constitute a decrease of 17 competing research project grants from those fundable under the 1986 level after sequestering. The total number of research project grants to be supported will be 442 within the rescission level.

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

3. Digestive Diseases and Nutrition

Impact Data

	1986 After Sequestering	1986 Revised Estimate	1987 Estimate
Research Project Grants			
Number......................	459	442	-17
Amount......................	$68,713,000	$67,268,000	-$1,445,000

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	1986 Proposed Rescission
4. Kidney Disease, Urology and Hematology...	$95,249,000	$91,083,000	$89,378,000	-$1,705,000

Purpose and Method of Operation

The NIDDK supports research efforts directed at understanding the normal and pathological structure and function of the cells and tissues of the kidney, urinary tract, and blood. Through advances in basic research, scientists are closer to defining and characterizing the causes of several diseases that affect these organs such as end-stage renal disease, glomerulonephritis, acute renal failure, urinary tract infection, benign prostatic hyperplasia, kidney stone disease, anemias of different origins, and disorders of blood cell production. This research will lead to prevention of these disorders and the development of alternative, more effective, and less costly therapies.

Rationale for the Proposed Rescission

The rescission of research project funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed funding level of $89,378,000 will provide $79,371,000 for the research project grant mechanism. This will constitute a decrease of 19 competing research project grants from those fundable under the 1986 level after sequestering. The total number of research project grants to be supported will be 522 within the rescission level.

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

4. Kidney Disease, Urology and Hematology

Impact Data

	1986 After Sequestering	1986 Revised Estimate	1987 Estimate
Research Project Grants			
Number	541	522	-19
Amount	$81,076,000	$79,371,000	-$1,705,000

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute of Neurological and Communicative Disorders and Stroke

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NATIONAL INSTITUTES OF HEALTH

National Institute of Neurological and Communicative Disorders and Stroke

Of the funds made available under this head in Public Law 99-178, $9,554,000 are rescinded.

National Institute of Neurological and Communicative Disorders and Stroke

Amounts Available for Obligation

1986 Appropriation..	$433,595,000
1986 Enacted administrative reduction........................	-233,000
1986 Sequester order...	-18,635,000
Proposed rescission..	-9,554,000
Subtotal, adjusted appropriation..........................	405,173,000
Unobligated balance lapsing.................................	-268,000
Total Obligations..	404,905,000

Summary of Changes

1986 Estimate..	433,094,000
1986 Sequester order..	-18,635,000
1986 Estimate after sequestering...........................	414,459,000
1986 Revised estimate...	404,905,000
Net change..	-9,554,000

	1986 Base	Change from Base
Decreases:		
Program:		
1. Research project grants.......	$281,619,000	-$9,554,000

National Institute of Neurological and Communicative Disorders and Stroke

Obligations by Activity

	1986 1/ 2/ Appropriation	1986 1/ 2/ after Sequestering	1986 1/ 2/ Revised Estimate	1986 Proposed Rescission
1. Biological basis research......	$220,242,000	$210,357,000	$203,676,000	-$6,681,000
2. Clinical research......	146,018,000	140,047,000	137,174,000	-2,873,000
3. All other.......	67,102,000	64,055,000	64,055,000	---
Total.........	433,362,000	414,459,000	404,905,000	-9,554,000

Obligations by Object

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	1986 Proposed Rescission
Other services......	$ 80,204,000	$ 76,594,000	$ 76,594,000	---
Grants, subsidies, and contributions.	353,158,000	337,865,000	328,311,000	-$9,554,000
Total, by object	433,362,000	414,459,000	404,905,000	-9,554,000

1/ Reflects an enacted administrative reduction of $233,000.

2/ Reflects a consultant services withholding (Section 515 of the Treasury-Postal Service Appropriation Act, 1985) of $268,000.

National Institute of Neurological and Communicative Disorders and Stroke

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
1. Biological Basis Research.....	$220,242,000	$210,357,000	$203,676,000	- $6,681,000

Purpose and Method of Operation

Biological Basis research is primarily responsible for stimulating and supporting research to provide new information on the structure and function of the neurological and communicative systems as a basis for development of methods for disease prevention. The underlying causes of most neurological and communicative disorders are not known at the present time. The disciplines involved include neurobiology, neurovirology, neurophysiology, neuropharmacology, and neurochemistry. More and more, multidisciplinary approaches to basic problems are proving to be productive. Communication among investigators and technology transfer are fostered by selective support of research workshops, symposia and conferences.

Studies of fundamental mechanisms in the nervous system not only provide the key to prevention, but in addition, develop the research techniques and methodologies that are adapted by clinical investigators. Research physicians are often trained in basic laboratories which provide the rationale and methods for studying the pathological process. Support is provided through research grants, Research Career Program awards, R&D contracts, and National Research Service Awards.

The Institute's research training budget supports Individual National Research Service Awards (NRSA) which are exclusively postdoctoral, and Institutional NRSAs which emphasize postdoctoral research training, but also provide support for a limited number of predoctoral trainees in selected research disciplines of national shortage.

Through the Research Career Program, specifically the Research Career Development Award (RCDA), the Institute promotes and supports career development of neurological and communicative scientists. Awards provide stipend support to enhance the research capability of individuals who, in the formative stages of their careers, have demonstrated outstanding potential for contributing as independent investigators to health-related research in the basic sciences.

Rationale for the Proposed Rescission

The rescission of research project grant funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed funding level for research project grants will be reduced from the 1986 level of 1,505 grants for $189,608,000 after sequestering, to a level of 1,467 grants for $182,927.000, a reduction of 38 grants and $6,681,000.

National Institute of Neurological and Communicative Disorders and Stroke

Biological Basis Research

Impact Data

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Research Project Grants			
Number.........	1,505	1,467	- 38
Amount........	$189,608,000	$182,927,000	- $6,681,000

National Institute of Neurological and Communicative Disorders and Stroke

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2. Clinical Research.....	$146,018,000	$140,047,000	$137,174,000	- $2,873,000

Purpose and Method of Operation

Clinical research uses the fundamental knowledge developed by basic research to clarify pathological conditions and to identify and pursue methods for amelioration, therapeutic intervention, and prevention of these conditions. Studies involve not only clinical investigations in humans, but also preclinical research aimed at development of disease models as well as development of a variety of diagnostic tests and prosthetic devices. The purpose of this research is to identify means for eliminating the causes of disorders or to provide more definitive treatment of these disorders. This program activity is supported through research grants, research centers, research career program awards, National Research Service Awards, and research and development contracts.

The Institute provides clinical research training through individual National Research Service Awards (postdoctoral fellowships) and institutional National Research Service Awards (training grants). These programs train personnel for academic careers in research aimed at developing improved diagnosis, treatment and, where possible, prevention of human nervous system and disorders of human communication (hearing and speech). Major areas of research training are: 1) medical neurology, neurosurgery, neuroepidemiology and neuropathology; 2) clinical communicative sciences, including otolaryngology, audiology, otopathology and speech pathology.

The Research Career Program, through Clinical Investigator Development Awards (CIDA), promotes and supports the development of research skills among physician scientists. This program seeks to recruit and prepare future physician investigators for academic research careers in the neurological and communicative sciences. Examples of such clinical areas include neurology, neurosurgery, neuroepidemiology, neuropathology, otolaryngology, audiology, and speech pathology. This award provides candidates with the opportunity for 3 to 5 years of special study and supervised experience tailored to individual capabilities and research interests. Successful applicants are individuals with high potential for academic and/or research careers in clinical areas. These awards bridge the gap between the early postdoctoral period and academic appointment.

Rationale for the Proposed Rescission

The rescission of research project grant funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed funding level for research project grants will be reduced from the 1986 level of 414 grants for $92,011,000 after sequestering, to a level of 404 grants for $89,138,000, a reduction of 10 grants and $2,873,000.

National Institute of Neurological and Communicative Disorders and Stroke

Clinical Research

Impact Data

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Research Project Grants			
Number........	414	404	- 10
Amount........	$92,011,000	$89,138,000	- $2,873,000

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases

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NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases

Of the funds made available under this head in Public Law 99-178, $1,513,000 are rescinded.

National Institute of Allergy and Infectious Diseases

Amounts Available for Obligation 1/

1986 Appropriation	$383,717,000
1986 Enacted administrative reduction	-265,000
1986 Sequester order	-16,488,000
Proposed rescission	-1,513,000
Subtotal, adjusted appropriation	365,451,000
Unobligated balance, start of year	553,000
Unobligated balance lapsing	-221,000
Total obligations	365,783,000

1/ Excludes $4,679,000 for reimbursable activities carried out by this account.

Summary of Changes

1986 Estimate	$383,784,000
1986 Sequester order	-16,488,000
1986 Estimate after sequestering	$367,296,000
1986 Revised estimate	365,783,000
Net change	-1,513,000

	1986 Base	Change from Base
Decreases:		
A. Program:		
1. Research project grants	$246,282,000	-$1,513,000

National Institute of Allergy and Infectious Diseases

Obligations by Activity

	1986 1/ Appropriation	1986 1/2/ after Sequestering	1986 1/2/ Revised Estimate	1986 Proposed Rescission
1. Immunology allergic and immunologic diseases......	$121,558,000	$116,463,000	$115,848,000	-$615,000
2. Microbiology and infectious diseases......	185,127,000	177,059,000	176,161,000	-898,000
3. All other.......	77,320,000	73,774,000	73,774,000	---
Total.......	384,005,000	367,296,000	365,783,000	-1,513,000

Obligations by Object

	1986 1/ Appropriation	1986 1/2 after Sequestering	1986 1/2/ Revised Estimate	1986 Proposed Rescission
Other services......	$103,813,000	$99,128,000	$99,128,000	---
Grants, subsidies, and contributions.	280,192,000	268,168,000	266,655,000	-$1,513,000
Total, by object.	384,005,000	367,296,000	365,783,000	-1,513,000

1/ Reflects an enacted administrative reduction of $265,000 and a carryover in unobligated funds of $553,000.

2/ Reflects a consultant services (Section 515 of the Treasury-Postal Service Appropriation Act, 1985) withholding of $221,000.

National Institute of Allergy and Infectious Diseases

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	1986 Proposed Rescission
1. Immunology allergic and immunologic diseases......	$121,558,000	$116,463,000	$115,848,000	-$615,000

Purpose and Method of Operation

The Immunology, Allergic and Immunologic Diseases Program supports research studies and research training on the structure and function of the immune system and its role in health and disease. Emphasis is placed on disorders of the immune system, such as asthma and other allergic diseases, congenital and acquired immune deficiencies, and immunoregulatory imbalances. Areas of concern also include natural mechanisms of disease resistance and cell-mediated immunity; drug-induced immunosuppression and other drug reactions; formation of antigen-antibody complexes in tissue, and their destructive pathologic consequences; autoimmune diseases; chronic disorders such as systemic lupus erythematosus, rheumatoid arthritis, and certain types of skin and kidney diseases; blood vessel conditions that impair the circulatory system, such as vasculitis; and a diverse group of diseases involving immunopathologic mechanisms affecting the metabolic, nervous, pulmonary and other systems in the body. Special consideration is being given to transplantation immunology, particularly to the mechanisms and prevention of graft rejection and graft-versus-host disease.

The major focus of this program is to develop new, fundamental knowledge of the immune system and its disorders through research project grants to individual scientists and through program projects to collaborative groups. The program project grants are focused on multidisciplinary studies of the biology of the immune system, mechanisms of immunologic diseases, and transplantation immunology.

Rationale for the Proposed Rescission

The rescission of research project grant funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed level of $115,848,000 for immunology, allergic and immunologic diseases will be used primarily for research project grants to fund approximately 610 awards; the funds rescinded account for a decrease of 23 new and competing renewal grants.

1. Immunologic, allergic and immunologic diseases

Impact data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Res. Proj. Grants			
Number	633	610	-23
Amount	$100,073,000	$99,458,000	-$615,000

National Institute of Allergy and Infectious Diseases

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	1986 Proposed Rescission
2. Microbiology and infectious diseases......	$185,127,000	$177,059,000	$176,161,000	-$898,000

Purpose and Method of Operation

The Microbiology and Infectious Diseases Program supports research with the broad aim of improving health by controlling diseases caused by infectious or parasitic agents. Projects range from studies of microbial physiology and antigenic structure to clinical trials of experimental drugs and vaccines. NIAID also supports studies on the mechanisms of resistance to antibiotics as well as research dealing with epidemiologic observations in hospitalized patients or community populations. Investigator-initiated research focuses on all aspects of microbiology, with particular emphasis on human pathogens. Areas of inquiry in basic microbiology include molecular anatomy and function, genetics, chemical composition, and physiologic and biochemical processes. Studies in bacteriology build on these data to identify immunizing antigens and to examine mechanisms of infection, pathogenicity, and virulence as related to such problems as hospital-associated infections and mycotic and sexually transmitted diseases. Areas of inquiry in virology include molecular structure, genetics, synthesis and reproduction, characterization of viral proteins and nucleic acids, mechanisms of pathogenicity, latency or persistence, reactivation, transformation and development of antiviral substances. This basic information is then applied to studies of the epidemiology, prevention and treatment of such diseases as influenza, genital herpes, hepatitis and diarrhea. Areas of inquiry in parasitology include biochemical, immunological and epidemiological studies of these much more complex multicellular organisms, along with studies directed toward biological control of their insect vectors.

Rationale for the Proposed Rescission

The rescission of research project grant funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed level of $176,161,000 for microbiology and infectious diseases will be devoted primarily to investigator-initiated research project grants to fund approximately 1,052 awards; the funds rescinded account for a decrease of 39 new and competing renewal grants.

2. Microbiology and infectious diseases

Impact data	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Res. Proj. Grants			
Number	1,091	1,052	-39
Amount	$146,209,000	$145,311,000	-$898,000

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTE OF HEALTH

National Institute of General Medical Sciences

FY 1986 Proposed Rescission

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NATIONAL INSTITUTE OF HEALTH

National Institute of General Medical Sciences

Of the funds made available under this head in Public Law 99-178, $7,358,000 are rescinded.

National Institute of General Medical Sciences

Amounts Available for Obligation

1986 Appropriation	$514,814,000
1986 Enacted administrative reduction	-49,000
1986 Sequester order	-22,135,000
Proposed rescission	-7,358,000
Subtotal, adjusted appropriation	485,272,000
Unobligated balance, start of year	1,171,000
Unobligated balance, lapsing	-237,000
Total obligations	486,206,000

Summary of Changes

1986 Estimate	515,699,000
1986 Sequester order	-22,135,000
1986 Estimate after sequestering	493,564,000
1986 Revised estimate	486,206,000
Net change	-7,358,000

	1986 base	Change from base
Decreases:		
Program:		
1. Research project grants	$411,268,000	-7,358,000

National Institute of General Medical Sciences

Obligations by Activity

	1986 Appropriation 1/	1986 Available after Sequestering 1/2/	1986 Revised Estimate 1/2/	1986 Proposed Rescission
1. Cellular and molecular basis of disease.......	$146,856,000	$140,473,000	$138,213,000	-$2,260,000
2. Genetics.......	171,327,000	164,354,000	161,652,000	-2,702,000
3. Pharmacological sciences......	74,366,000	71,057,000	69,958,000	-1,099,000
4. Biophysics and physiological sciences......	101,263,000	96,167,000	94,870,000	-1,297,000
5. All other.....	22,124,000	21,513,000	21,513,000	0
Total obligations.	515,936,000	493,564,000	486,206,000	-7,358,000

Obligations by Object

	1986 Appropriation	1986 Available after Sequestering	1986 Revised Estimate	1986 Proposed Rescission
Grants, subsidies, and contributions..	$500,499,000	$478,792,000	$471,434,000	-$7,358,000
All other......	15,437,000	14,772,000	14,772,000	---
Total, by object....	515,936,000	493,564,000	486,206,000	-7,358,000

1/ Reflects an enacted administrative reduction of $49,000 and a carryover in unobligated funds of $1,171,000.

2/ Reflects a consultant services (Section 515 of the Treasury-Postal Service Appropriation Act, 1985) withholding of $237,000.

National Institute of General Medical Sciences

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
1. Cellular and Molecular Basis of Disease......	$146,856,000	$140,473,000	$138,213,000	-$2,260,000

Purpose and Method of Operation

The cell is the fundamental biological unit of all living organisms. It holds the capacity for generating, from simple exogenous sources, all its macromolecules (e.g., proteins, RNA and DNA), energy, and complex organization and structure. The Cellular and Molecular Basis of Disease (CMBD) Program is concerned with basic questions about the functions of cells and their components. The research and research training supported by this program encompass a wide range of scientific efforts, from cell-cell communication, cell adhesion, and development, to cellular metabolism, energetics, mechanisms of enzyme action, and the molecular structure of cells. Ranging as it does from the molecular to the multicellular, this research is broad in scope, and utilizes a wide variety of both traditional and emerging technologies, instruments, and models. Results from this basic cellular and molecular research continue to contribute to our expanding knowledge about how a healthy body functions and why disease occurs.

Recognition of this contribution came again this year in the award of the 1985 Nobel Prize for Physiology or Medicine to Drs. Michael Brown and Joseph Goldstein, whose early work on cholestoral receptors was supported by the CMBD Program. This early work led to their subsequent investigations of the genetic basis of, and potential therapies for, familial hypercholesterolemia, a serious and often fatal genetic disorder tied to defects in these receptors.

Rationale for the Proposed Rescission

The rescission of $2,260,000 in research project grant funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed funding level of $138,213,000 will provide 824 research project grants, one research center, 4 other research awards, 1,265 trainees and 2 research and development contracts. The proposed rescission of $2,260,000 will reflect a reduction of 44 research project grants.

1. Cellular and Molecular Basis of Disease

Impact Data

	1986 Available after Sequestering	1986 Revised Estimate	Proposed Rescission
Res. proj. grants			
Number	868	824	-44
Amount	$118,277,000	$116,017,000	-$2,260,000

National Institute of General Medical Sciences

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2. Genetics............	$171,327,000	$164,354,000	$161,652,000	-$2,702,000

Purpose and Method of Operation

The Genetics Program is responsible for providing financial support for basic research studies concerned with elucidating the fundamental mechanisms of inheritance. Such research is designed to develop information needed by researchers seeking to discover effective methods for the diagnosis, treatment, and prevention of the more than 3,000 genetic disorders which are known to afflict mankind.

Genetic disorders account for a major portion of the diseases and deaths recorded in the United States each year, with an estimated 6 percent of the U.S. population suffering from a genetic disorder which can be described as severe. Illustrative is the case of Lesch-Nyhan syndrome, an inherited disease brought on by the presence of a simple defect in just one of the estimated 100,000 genes possessed by humans. This inherited defect prevents the normal production by the body of an enzyme called HPRT (hypoxanthineguanine-phosphoribosyl transferase). Victims of this disease tend to be mentally retarded; they have to be restrained to avoid self-mutilation; and they seldom live beyond their 20th birthday. Other inherited disorders (e.g., Down's syndrome, cystic fibrosis, Tay-Sachs disease, Huntington's disease, and sickle cell anemia), many of which are also caused by a single genetic defect, have similarly devastating effects—destroying both individuals and families, while placing an enormous financial burden on our health care system. Indeed, an estimated 15-20 percent of all health care costs are associated in some way with genetic disease.

Rationale for the Proposed Rescission

The rescission of $2,702,000 in research project grant funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed funding level of $161,652,000 will provide 955 research project grants, 3 research centers, 10 other research awards, 197 trainees, and 3 research and development contracts. The proposed rescission of $2,702,000 will reflect a reduction of 47 research project grants.

2. Genetics

Impact Data

	1986 Available after Sequestering	1986 Revised Estimate	Proposed Rescission
Res. proj. grants			
Number	1,002	955	-47
Amount	$155,294,000	$152,592,000	-$2,702,000

National Institute of General Medical Sciences

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
3. Pharmacological Sciences...........	$74,366,000	$71,057,000	$69,958,000	-$1,099,000

Purpose and Method of Operation

The Pharmacological Sciences (PS) Program supports a broad spectrum of research aimed at providing an improved understanding of the biological phenomena and related chemical and molecular processes involved in the actions of therapeutic drugs and anesthetics. The scope of the program ranges from chemical syntheses and molecular pharmacology to controlled studies of the effects of drugs in man. Much of the research supported by the Program integrates such fields as genetics, endocrinology, chemistry, and computer science with the more traditional areas of pharmacological investigation in an effort to characterize molecular interactions and to understand their expression in man. While substantial portions of the PS Program budget support work in anesthesiology and pharmacology, the most significant expenditures are for research in biorelated chemistry. Within this broad field, research in basic chemistry predominates -- in recognition of the importance of such work to the design and synthesis of a wide variety of compounds of potential health-related use. A major thrust of the basic research supported by the Pharmacological Sciences Program is concerned with determining how pharmacologically active substances exert their effects, so that side effects can be minimized and new and better drugs can be developed.

Rationale for the Proposed Rescission

The rescission of $1,099,000 in research project grant funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed funding level of $69,958,000 will provide 454 research project grants, 4 research centers, 9 other research awards and 311 trainees. The proposed rescission of $1,099,000 will reflect a reduction of 27 research project grants.

3. Pharmacological Sciences

Impact Data

	1986 Available after Sequestering	1986 Revised Estimate	Proposed Rescission
Res. proj. grants			
Number	481	454	-27
Amount	$63,153,000	$62,054,000	-$1,099,000

National Institute of General Medical Sciences

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
4. Biophysics and Physiological Sciences........	$101,263,000	$96,167,000	$94,870,000	-$1,297,000

Purpose and Method of Operation

The Biophysics and Physiological Sciences (BPS) Program supports basic biomedical research studies directed toward three primary goals: (1) gaining a better understanding of the structures and functions of biologically important molecules, such as proteins, through the use of theories and tools common to physics; (2) the development of new methods and instrumentation for use in molecular and cellular analyses; and (3) gaining an in-depth knowledge of the physiological effects of severe burns and other forms of trauma on the body, with an eye toward developing information useful to the clinical care of individuals suffering from such trauma.

The BPS Program was established just one year ago, by the expansion of the existing Physiology and Biomedical Engineering Program to include aspects of biophysics previously distributed through other programs within the Institute. Central to the rationale for this reorganization was the rapid growth in recent years of research opportunities in the biophysical sciences field--prompted by advances in research instrumentation--and the consequent need to provide a central focus within the NIGMS for such research. Investigators in this field are now convinced that the growing ability to identify the precise nature of structural abnormalities at the molecular level (e.g., defects in proteins), as well as the effects of such abnormalities, represents a critical step in the battle against diseases because it will allow effective therapies to be developed.

Rationale for the Proposed Rescission

The rescission of $1,297,000 in research project grant funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed funding level of $94,870,000 will provide 548 research project grants, 7 research centers, 9 other research awards and 857 trainees. The proposed rescission of $1,297,000 will reflect a reduction of 44 research project grants.

4. Biophysics and Physiological Sciences

Impact Data

	1986 Available after Sequestering	1986 Revised Estimate	Proposed Rescission
Res. proj. grants			
Number	592	548	-44
Amount	$74,544,000	$73,247,000	-$1,297,000

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTE OF HEALTH

National Institute of Child Health and Human Development

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NATIONAL INSTITUTE OF HEALTH

National Institute of Child Health and Human Development

Of the funds made available under this head in Public Law 99-178, $1,150,000 are rescinded.

National Institute of Child Health and Human Development

Amounts Available for Obligation

1986 Appropriation	$321,972,000
Enacted administrative reduction	-176,000
1986 Sequester order	-13,838,000
Proposed rescission	-1,150,000
Subtotal, adjusted appropriation	306,808,000
Unobligated balance, start of year	486,000
Unobligated balance, end of year	-215,000
Total obligations	307,079,000

Summary of Changes

1986 Estimate	322,067,000
1986 Sequester order	-13,838,000
1986 Estimate after sequestering	308,229,000
1986 Revised estimate	307,079,000
Net change	-1,150,000

	1986 Base	Change from Base
Decreases:		
Program:		
1. Research project grants	$190,665	-$1,150

National Institute of Child Health and Human Development

Obligations by Activity

	1986 1/ Appropriation	1986 after 1/ 2/ Sequestering	1986 Revised 1/ 2/ Estimate	1986 Proposed Rescission
1. Research for Mothers & Children..	$165,489,000	$157,972,000	$157,272,000	-$700,000
2. Population..........	105,923,000	101,790,000	101,340,000	-450,000
3. All other...........	50,870,000	48,467,000	48,467,000	---
Total...............	322,282,000	308,229,000	307,079,000	-1,150,000

Obligations by Object

	1986 1/ Appropriation	1986 after 1/ 2/ Sequestering	1986 Revised 1/ 2/ Estimate	1986 Proposed Rescission
Other services..........	$74,022,000	$70,623,000	$70,623,000	---
Grants, subsidies, and contributions.........	248,260,000	237,606,000	236,456,000	-1,150,000
Total, by object......	322,282,000	308,229,000	307,079,000	-1,150,000

Note: 1/ Reflects an enacted administrative reduction of $176,000 and a carryover in unobligated funds of $486,000.

2/ Reflects a consultant services (Section 515 of the Treasury-Postal Service Appropriation Act, 1985) withholding of $215,000.

National Institute of Child Health and Human Development

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
1. Research for Mothers & Children..	$165,489,000	$157,972,000	$157,272,000	-$700,000

Purpose and Method of Operations

Since 1962, the National Institute of Child Health and Human Development (NICHD) has dedicated itself to studying ways to improve the health of mothers and children. It supports and conducts research directed toward ensuring the optimal outcome of pregnancy and toward maximizing the health potential of the 3.7 million infants born in the U.S. each year.

The Center for Research for Mothers and Children (CRMC) is the primary extramural program supporting research on maternal and child health at the NICHD and at the National Institutes of Health. CRMC research encompasses morbidity, the role of nutrients and hormones in growth and development, the causes and prevention of mental retardation, and the learning and cognitive processes involved in behavioral development.

Two-thirds of all infant deaths occur among low birth weight infants. With today's improved neonatal intensive care, most infants of 1,500 to 2,500 grams survive and do fairly well but infants born weighing less than 1,500 grams do not fare as well. These infants require long periods of intensive care and some have life-long residual effects. Low birth weight may be due to intrauterine growth retardation, premature labor, or both.

Rationale for the Budget Request

The rescission of research project grant funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed funding level of $157,272,000 includes $122,370,000 to fund 804 research project grants, at an average cost of $152,000 per grant. The amount rescinded, $700,000, will be accompanied by a reduction of 10 research project grants.

National Institute of Child Health and Human Development

205

1. Research for Mothers and Children

Impact Data

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Research Projects Grants			
Numbers..................	814	804	-10
Amount...................	123,070,000	122,370,000	-700,000

National Institute of Child Health and Human Development

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
2. Population.........	$105,923,000	$101,790,000	$101,340,000	-$450,000

Purpose and Method of Operations

The NICHD Center for Population Research (CPR) is responsible for the primary Federal research program in the areas of reproductive biology, population dynamics and contraceptive development and evaluation. Fundamental biomedical research in the reproductive sciences relevant to the problems of human fertility and infertility is emphasized. This research provides the bases for the development of safe and efficacious methods for fertility regulation and the evaluation of the benefits and risks of current contraceptive methods. Demographic and behavioral sciences research on the causes and consequences of population structure and change is also supported. Funding is provided through grants and contracts and includes the support of population research centers and research training.

Rationale for the Budget Request

e rescission of research project grant funds is a necessary transition to the spending
vels in the President's FY 1987 budget.

The proposed funding level of $101,340,000 includes $67,145,000 to fund 554 research project grants, at an average cost of $121,200 per grant. The amount rescinded, $450,000, will be accompanied by a reduction of 6 research project grants.

National Institute of Child Health and Human Development

2. Population

Impact Data

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Research Projects Grants			
Numbers....................	560	554	-6
Amount..................	67,595,000	67,145,000	-450,000

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTE OF HEALTH

National Eye Institute

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NATIONAL INSTITUTE OF HEALTH

National Eye Institute

Of the funds made available under this head in Public Law 99-178, $5,224,000 are rescinded.

National Eye Institute

Amounts Available for Obligation

1986 Appropriation	$195,168,000
1986 Enacted administrative reduction	-74,000
1986 Sequester order	-8,389,000
Proposed rescission	-5,224,000
Subtotal, adjusted appropriation	181,481,000
Unobligated balance, start of year	78,000
Unobligated balance lapsing	-101,000
Total obligations	181,458,000

Summary of Changes

1986 Estimate	$195,071,000
1986 Sequester order	-8,389,000
1986 Estimate after sequestering	186,682,000
1986 Revised estimate	181,458,000
Net change	-5,224,000

	1986 Base	Change from Base
Decreases:		
Program:		
1. Research project grants	$142,994,000	-$5,224,000

National Eye Institute

Obligations by Activity

	1986 Appropriation 1/	1986 after Sequestering 1/2/	1986 Revised Estimate 1/2/	1986 Proposed Rescission
1. Retinal & Choroidal Diseases....	$77,300,000	$73,401,000	$71,228,000	$-2,173,000
2. Corneal Diseases....	28,200,000	27,188,000	26,253,000	-935,000
3. Cataract......	14,254,000	13,792,000	13,311,000	-481,000
4. Glaucoma......	15,830,000	15,300,000	14,731,000	-569,000
5. Strabismus, Amblyopia & Visual Processing..	34,189,000	32,796,000	31,730,000	-1,066,000
6. All other.....	25,399,000	24,205,000	24,205,000	--
Total.......	195,172,000	186,682,000	181,458,000	-5,224,000

Obligations by Object

	1986 Appropriation 1/	1986 after Sequestering 1/2/	1986 Revised Estimate 1/2/	1986 Proposed Rescission
Other object classes.........	$28,748,000	$27,410,000	$27,410,000	--
Grants, subsidies, and contributions...	166,424,000	159,272,000	154,048,000	-5,224,000
Total by object......	195,172,000	186,682,000	181,458,000	-5,224,000

1/ Reflects an enacted administrative reduction of $74,000 and a carryover in unobligated funds of $78,000.

2/ Reflects a consultant services (Section 515 of the Treasury-Postal Service Appropriation Act, 1985) withholding of $101,000.

National Eye Institute

	1986 Appropriation	1986 Available after Sequestering	1986 Revised Estimate	Proposed Rescission
1. Retinal and Choroidal Diseases....	$77,300,000	$73,401,000	$71,228,000	-$2,173,000

Purpose and Method of Operation

Under this program, NEI supports basic and applied studies on the structure and function of the retina in health and disease. Included are studies on blood vessel abnormalities such as diabetic retinopathy, inflammatory disorders, tumors, developmental and hereditary disorders, macular degeneration, retinal detachment, environmentally-induced disorders, and the functioning of the photoreceptors. Research is funded by grants and contracts, cooperative agreements, institutional training grants, and individual fellowships.

Rationale for the Proposed Rescission

The rescission of research project grant funds is a necessary transition to the spending levels in the President FY 1987 budget.

The proposed funding level of $71,228,000 includes $56,014,000 for 439 research project grants as compared to $58,187,000 for 451 grants at the sequestration level.

National Eye Institute

1. Retinal and Choroidal Diseases

Impact Data

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Research project grants			
Number	451	439	-12
Amount	$58,187,000	$56,014,000	-$2,173,000

National Eye Institute

	1986 Appropriation	1986 Available after Sequestering	1986 Revised Estimate	Proposed Rescission
2. Corneal Diseases....	$28,200,000	$27,188,000	$26,253,000	-$935,000

Purpose and Method of Operation

This program encompasses research on diseases of the cornea--the transparent structure at the front of the eye that helps focus incoming light rays--and of the external ocular structures, including conjunctiva and lids. Because the cornea is the most exposed surface of the eye, it is particularly vulnerable to damage from injury, infection, toxic agents, and environmental pollutants.

The Corneal Diseases program of the National Eye Institute is divided into the following five subprograms: external ocular infections and inflammatory diseases, ocular surface problems, refractive problems and contact lenses, corneal edema, and corneal transplantation and wound healing. Research is funded by grants and contracts, cooperative agreements, institutional training awards, and individual fellowships.

Rationale for the Proposed Rescission

The rescission of research project grant funds is a necessary transition to the spending levels in the President FY 1987 budget.

The proposed funding level of $26,253,000 includes $24,844,000 for 180 research project grants as compared to $25,779,000 for 185 grants at the sequestration level.

2. Corneal Diseases

Impact Data

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Research project grants			
Number	185	180	-5
Amount	$25,779,000	$24,844,000	-$935,000

	1986 Appropriation	1986 Available after Sequestering	1986 Revised Estimate	Proposed Rescission
3. Cataract......	$14,254,000	$13,792,000	$13,311,000	-$481,000

Purpose and Method of Operation

A cataract is a cloudy or opaque area in the eye's lens that can develop over a period of years or within just a few months. If the lens becomes clouded with a cataract, the passage of light is obstructed and vision may be impaired. A cataract results from complex changes in the chemical composition of the lens, which scientists only partially understand.

NEI's Cataract Program supports studies on how and why cataracts develop, ways to prevent cataracts or slow their progress, the safety and effectiveness of new surgical and other techniques for treating cataracts, and better methods to correct vision after cataract surgery. Research in this program is funded through research grants and contracts, cooperative agreements, institutional training awards, and individual fellowships.

Rationale for the Proposed Rescission

The rescission of research project grant funds is a necessary transition to the spending levels in the President FY 1987 budget.

The proposed funding level of $13,311,000 includes $12,943,000 for 115 research project grants as compared to $13,424,000 for 118 grants at the sequestration level.

National Eye Institute

3. Cataract

Impact Data

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Research project grants			
Number	118	115	-3
Amount	$13,424,000	$12,943,000	-$481,000

National Eye Institute

	1986 Appropriation	1986 Available after Sequestering	1986 Revised Estimate	Proposed Rescission
4. Glaucoma......	$15,830,000	$15,300,000	$14,731,000	-$569,000

Purpose and Method of Operation

Glaucoma usually occurs when the out flow of aqueous humor, a fluid constantly produced in the eye is impaired leading to an excessive level of pressure within the eye. The building of pressure gradually destroys the optic nerve, which carries visual messages to the brain and allows sight. This damage is irreversible.

The Glaucoma Program promotes research on preventing blindness from glaucoma through studies of the optic nerve, improving methods of lowering intraocular pressure, developing methods for very early detection and treatment of glaucoma, and predicting its clinical course. These objectives are accomplished through research project grants and contracts, cooperative agreements, individual fellowships, and institutional training awards.

Rationale for the Proposed Rescission

The rescission of research project grant funds is a necessary transition to the spending levels in the President FY 1987 budget.

The proposed funding level of $14,731,000 includes $14,579,000 for 107 research project grants as compared to $15,148,000 for 108 grants at the sequestration level.

National Eye Institute

4. Glaucoma

Impact Data

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Research project grants			
Number	108	107	-1
Amount	$15,148,000	$14,579,000	-$569,000

National Eye Institute

	1986 Appropriation	1986 Available after Sequestering	1986 Revised Estimate	Proposed Rescission
5. Strabismus, Amblyopia & Visual Processing..	$34,189,000	$32,796,000	$31,730,000	-$1,066,000

Purpose and Method of Operation

The Strabismus, Amblyopia, and Visual Processing program promotes and supports research on the structure, function, and development of the ocular muscles and those portions of the brain that make vision possible. This research is directed toward gaining a better understanding of normal vision and of the causes of visual deficits and blindness that do not appear to result from specific dysfunction of the eye itself. This program is funded through research grants and contracts, cooperative agreements, institutional training awards, and individual fellowships.

Rationale for the Proposed Rescission

The rescission of research project grant funds is a necessary transition to the spending levels in the President FY 1987 budget.

The proposed funding level of $31,730,000 includes $29,390,000 for 273 research project grants as compared to $30,456,000 for 279 grants at the sequestration level.

National Eye Institute

5. Strabismus, Amblyopia and Visual Processing

	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Research project grants			
Number........................	279	273	-6
Amount........................	$30,456,000	$29,390,000	-$1,066,000

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTE OF HEALTH

National Institute on Aging

FY 1986 Proposed Rescission

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NATIONAL INSTITUTE OF HEALTH

National Institute on Aging

Of the funds made available under this head in Public Law 99-178, $2,679,000 are rescinded.

National Institute on Aging

Amounts Available for Obligation

1986 Appropriation	$156,592,000
1986 Enacted administrative reduction	-101,000
1986 Sequester order	-6,729,000
Proposed rescission	-2,679,000
Subtotal, adjusted appropriation	147,083,000
Unobligated balance, start of year	1,323,000
Unobligated balance, lapsing	-139,000
Total obligations	148,267,000

Summary of Changes

1986 Estimate	$157,675,000
1986 Sequester order	-6,729,000
1986 Estimate after sequestering	150,946,000
1986 Revised estimate	148,267,000
Net change	-2,679,000

	1986 Base	Change from base
Decreases:		
Program:		
1. Research project grants	$88,771,000	-$2,679,000

National Institute on Aging

Obligations by Activity

	1986 1/ Appropriation	1986 Available 1/ after 2/ sequestering	1986 Revised 1/ Estimate 2/	1986 Proposed Rescission
1. Aging..........	$128,547,000	$123,076,000	$120,397,000	-$2,679,000
2. All other....	29,267,000	27,870,000	27,870,000	--
Total......	157,814,000	150,946,000	148,267,000	-2,679,000

Obligations by Object

	1986 1/ Appropriation	1986 Available 1/ after 2/ sequestering	1986 Revised 1/ Estimate 2/	1986 Proposed Rescission
Other services.....	$43,000,000	$41,012,000	$41,012,000	--
Grants, subsidies, and contributions..	114,814,000	109,934,000	107,255,000	-2,679,000
Total, by object.	157,814,000	150,946,000	148,267,000	-2,679,000

1/ Reflects an administrative reduction of $101,000 and a carryover in unobligated funds of $1,323,000.

2/ Reflects a consultant services (Section 515 of the Treasury-Postal Service Appropriation Act, 1985) withholding of $139,000.

National Institute on Aging

	1986 Appropriation	1986 Available after sequestering	1986 Revised Estimate	Increase or decrease
1. Aging....	$128,547,000	$123,076,000	$120,397,000	-$2,679,000

Purpose and Method of Operation

The aging activity supports a multidisciplinary extramural research and training effort at universities, medical schools, hospitals and other institutions throughout the United States. Through this research the NIA seeks to develop a better understanding of biomedical, behavioral and social aging processes, to differentiate between the normal aging processes and disease states common to the elderly, and to achieve more understanding of the problems of older people. The long-range goal of these efforts, is to delay or avoid many of the debilitating effects of age, with consequent savings in both personal anguish and health expenditures. The aging activity consists of three programs: biomedical and clinical research; behavioral sciences research; and epidemiology, demography, and biometry.

The biomedical and clinical research program focuses on research related to the basic mechanisms of aging; normal changes in function with age; and clinical problems such as Alzheimer disease, urinary incontinence, and infections in older persons. The behavioral sciences program supports research on the psychological and social aspects of aging as a process; the behavior, attitudes, and status of older people; the relationships between aging individuals and society as a whole; and how these effect health and disease in older people. The epidemiology, demography, and biometry program coordinates and conducts quantitative population-based research on health and disease in the aged, as well as demographic and economic analyses.

Rational for the Proposed Rescission

The rescission of research project grant funds is a necessary transition to the spending levels in the President's FY 1987 budget.

The proposed funding level will support 177 new and competing research project grants at a level of $28,425,000 compared with 201 competing grants at a level of $31,104,000 after sequestering. Funding for 303 noncompeting research project grants will remain stable at $57,544,000, as will funding for all other mechanisms within the Aging activity.

National Institute on Aging

1. Aging

Impact Data	1986 Available after sequestering	1986 Revised estimate	Proposed Rescission
Res. Project Grants			
Number..........................	504	480	-24
Amount..........................	$88,771,000	$86,092,000	-$2,679,000

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTE OF HEALTH

Office of the Director

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NATIONAL INSTITUTE OF HEALTH

Office of the Director

Of the funds made available under this head in Public Law 99-178, $23,055,000 are rescinded.

Office of the Director

Amounts Available for Obligation

1986 Appropriation	$117,085,000
1986 Enacted administrative reduction	-93,000
1986 Sequester order	-5,031,000
Proposed rescission	-23,055,000
Subtotal, adjusted appropriation	88,906,000
Unobligated balance, start of year	+2,779,000
Unobligated balance lapsing	-2,000
Total obligations	91,683,000

Summary of Changes

1986 Estimate	$119,769,000
1986 Sequester order	-5,031,000
1986 Estimate after sequestering	114,738,000
1986 Revised estimate	91,683,000
Net change	-23,055,000

	1986 Base	Change from Base
Decreases:		
A. Program:		
1. Research grants	$86,130,000	-$23,055,000

Office of the Director

Obligations by Activity

	1/ 1986 Appropriation	1986 1/2/ after Sequestering	1986 1/2/ Revised Estimate	1986 Proposed Rescission
1. Academic research enhancement award program..	$10,000,000	$9,570,000	$5,000,000	-$4,570,000
2. Research center in minority institutions...	10,000,000	9,570,000	5,000,000	-4,570,000
3. Acquired immune deficiency syndrome res...	70,000,000	66,990,000	53,075,000	-13,915,000
3. All other........	29,769,000	28,608,000	28,608,000	---
Total........	119,769,000	114,738,000	91,683,000	-23,055,000

Obligations by Object

	1/ 1986 Appropriation	1986 1/2/ after Sequestering	1986 1/2/ Revised Estimate	1986 Proposed Rescission
Other services.......	$29,769,000	$28,608,000	$28,608,000	---
Grants, subsidies, and contributions..	90,000,000	86,130,000	63,075,000	-23,055,000
Total, by object..	119,769,000	114,738,000	91,683,000	-23,055,000

1/ Reflects an enacted administrative reduction of $93,000 and a carryover in unobligated funds of $2,779,000.

2/ Reflects a consultant services (Section 515 of the Treasury-Postal Service Appropriation Act, 1985) withholding of $2,000.

Office of the Director

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	1986 Proposed Rescission
1. Academic research enhancement award program..	$10,000,000	$9,570,000	$5,000,000	-$4,570,000

Purpose and Method of Operation

The Academic Research Enhancement Award Program (AREA) is intended to strengthen the research milieu of non-research-intensive, four-year colleges and universities and provide undergraduate training for a significant number of our nation's research scientists. AREA grants, which are transferred to individual BIDs for award and administration, enable qualified individual scientists within eligible institutions to carry out health-related feasibility studies, pilot studies and other small-scale research projects.

Rationale for the Proposed Rescission

A rescission of $4,570,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending and thereby control one source of inflationary pressure. These funds were appropriated in excess of the President's request for this program.

Office of the Director

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	1986 Proposed Rescission
2. Research center in minority institutions...	$10,000,000	$9,570,000	$5,000,000	-$4,570,000

Purpose and Method of Operation

The Research Centers in Minority Institutions Program (RCMI) was developed to establish research centers in those predominantly minority institutions which offer doctoral degrees in the health professions or the sciences related to health. The RCMI grants are intended to enhance significantly the capacity of such institutions for the conduct of biomedical and/or behavioral research by strengthening and augmenting both their human and physical resources.

Rationale for the Proposed Rescission

A rescission of $4,570,000 is proposed as part of the President's overall budget reform plan to curtail Federal Government spending and thereby control one source of inflationary pressure. These funds were appropriated in excess of the President's request for this program.

Office of the Director

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	1986 Proposed Rescission
3. Acquired immune deficiency syndrome res...	$70,000,000	$66,990,000	$53,075,000	-$13,915,000

Purpose and Method of Operation

Since the spring of 1984 when scientists discovered the virus that causes acquired immunodeficiency syndrome (AIDS), NIH has directed its efforts toward other important research questions aimed at preventing, treating, and curing the disease. Several NIH components are involved in AIDS research, through support of extramural projects and/or intramural studies.

Building on a strong foundation of basic knowledge in immunology, virology, and molecular biology, scientists involved in AIDS research have advanced our undertsanding of AIDS greatly in the four years since the identification of the disease. In addition, a long-standing national commitment to training research scientists has assured the existence of a cadre of researchers around the country who have been ready to apply their expertise to the challenges posed by AIDS.

Currently, the NIH effort against AIDS is primarily aimed at development of agents to treat the disease and vaccines to prevent it. Important adjuvant research includes continued epidemiologic studies of the natural history of the disease, and a variety of basic research studies are ongoing.

Major program initiatives are being undertaken in 1986 to expedite the discovery, development, and testing of drugs against AIDS, with particular emphasis on the involvement of the extramural scientific/medical community and additional AIDS patients in these efforts.

Rationale for the Proposed Rescission

The Congress provided $70,000,000 for AIDS research in the appropriation of the Office of the Director for allocation to the Institutes in response to emerging opportunities. The rescission would reduce this amount to $53,075,000, $13,915,00 below the amount available after sequestering. At this level, the new initiatives proposed by NCI, NIDR, and NIAID in September 1985 would be funded; these programs include a major new collaborative effort in drug development and evaluation, involving screening, preliminary clinical studies, and full scale testing with AIDS patients in 10 Drug Treatment Evaluation Units to be established throughout the country in 1986.

Among the areas that have been approved at NIH, but will not be funded under the revised budget, are the following: additional evaluations of current blood screening tests and development of new ones ($4.7 million); the establishment of a National Chimpanzee Management Plan designed to create a dedicated reserve of breeding animals to guarantee a supply of chimpanzees, which constitute the only currently available animal model for testing AIDS vaccines ($4.5 million); expanded vaccine efforts ($3.1 million); and additional studies on AIDS transmission ($.7 million). All areas will be continually reviewed to assure effective allocation and use of the available funds.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

Alcohol, Drug Abuse, and Mental Health

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ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH

Of the funds made available under this head in Public Law 99-178, $39,718,000 are rescinded.

Alcohol, Drug Abuse, and Mental Health

Amounts Available for Obligation

1986 Appropriation	$968,860,000
1986 Sequester order	-41,661,000
Proposed rescission	-39,718,000
Subtotal, adjusted appropriation	887,481,000
Unobligated balance, start of year	1,220,000
Unobligated balance, lapsing	-1,092,000
Total obligations	$887,609,000

Summary of Changes

1986 Estimate	$968,860,000
1986 Sequester order	-41,661,000
1986 Estimate after sequestering	927,199,000 1/
1986 Revised estimate	887,481,000
Net change	-$39,718,000

	1986 base	Change from base
Decreases:		
Program:		
General Mental Health:		
1. Planning & Demonstration - elimination of program	$11,962,000	-$11,008,000
2. Protection and Advocacy - elimination of program	9,570,000	-9,570,000
3. Clinical Training - elimination of program	19,140,000	-19,140,000
Subtotal	---	-39,718,000
Net change	$---	-$39,718,000

1/ Includes comparable amount of $12,157,000 for AIDS and $1,092,000 to be withheld as required by the Treasury, Postal Service, and General Government Appropriations Act, 1986.

Alcohol, Drug Abuse, and Mental Health

Budget Authority by Activity

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate 1/	1986 Proposed Rescissions
1. Mental Health:				
Planning & Demonstration..	$12,500,000	$11,962,000	$954,000	-$11,008,000
Protection & Advocacy.....	10,000,000	9,570,000	---	-9,570,000
Clinical Training.........	20,000,000	19,140,000	---	-19,140,000
2. All Other.................	926,360,000	886,527,000	886,527,000	---
Total, budget authority..	$968,860,000	$927,199,000	$887,481,000	-$39,718,000

Budget Authority by Object

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate 1/	1986 Proposed Rescissions
Other services................	$46,800,000	$43,800,000	$42,977,000	-$823,000
Project contracts...........	24,876,000	23,389,000	22,944,000	-445,000
rants, subsidies, and contributions...............	808,897,000	773,937,000	735,487,000	-38,450,000
All other.....................	88,287,000	86,073,000	86,073,000	---
Total, by object.........	$968,860,000	$927,199,000	$887,481,000	-$39,718,000

1/ The comparable transfer of $12,157,000 in AIDS funding to the Office of the Assistant Secretary for Health has not been deducted from this estimate.

Alcohol, Drug Abuse, and Mental Health Administration

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	1986 Proposed Rescissions
Mental Health:				
Planning & Demonstration....	$12,500,000	$11,962,000	$954,000	-$11,008,000
Protection & Advocacy.......	10,000,000	9,570,000	---	-9,570,000
Clinical Training...........	20,000,000	19,140,000	---	-19,140,000
Total.....................	$42,500,000	$40,672,000	$954,000	-$39,718,000

General Statement

This action covers funds appropriated under the Department of Labor, Health and Human Services, Education and Related Agencies Appropriation Act, 1986, P.L. 99-178, for the continuation of the National Institute of Mental Health's clinical training program, the community support program (CSP), and the implementation of the protection and advocacy program. The funds are being proposed for rescission in 1986 as part of the President's overall budget reform plan to curtail Federal Government spending and thereby control one source of both inflationary and budget deficit pressure. The amount remaining in 1986 for the CSP will allow the Institute to meet obligations incurred prior to submission of the rescission proposal.

The community support program is a demonstration program designed to promote the development of community support systems for the chronically mentally ill and improve the quality and appropriateness of services and opportunities for this population. There are two principal segments to the program: the adult program and the Child and Adolescent Service System Program (CASSP). The adult program concentrates on those individuals who are inappropriately institutionalized in hospitals and nursing homes, and the larger number of such individuals who are living outside of hospitals without adequate housing or life support services. The CASSP addresses the availability of a complete system of care for mentally disturbed children and youth in communities through involvement of the States in a leadership role. These demonstration programs have been supported as such since 1979. The Administration position is that they have done an excellent job of demonstrating the importance of these efforts and the usefulness of appropriate approaches in addressing these populations and now should be phased out. As with other ADM services efforts, these can be picked up by the local community to the extent they are necessary and effective. Currently ADAMHA provides $490,000,000 block grant funds to the States to support services programs they deem beneficial.

In its final action on the 1986 appropriations bill for ADAMHA the Congress provided $10,000,000 for a new program of protection and advocacy for the mentally ill, consistent with the provisions of S. 974 as passed by the Senate on July 31, 1985. The Administration did not request any funds for this purpose. The program would duplicate States' capacities to protect mentally ill persons from abuse and neglect. Currently no authorizing legislation exists. The Administration believes that States have the capacity to monitor care of the mentally ill.

When the NIMH clinical training program was established 35 years ago there were only 5,000 psychiatrists in the country and most medical schools did not have independent departments of psychiatry. The profession of clinical psychology was in its infancy and there was no graduate level specialty in psychiatric nursing. Social work had not developed a focus on mental health. NIMH support was instrumental in building academic mental health training departments, improving the quality of training, and greatly increasing the numbers of mental health professionals. For example:

- o Today there are over 31,000 psychiatrists, including 3,200 child psychiatrists.
- o There are now approximately 7,000 psychiatric nurses and the field has status as a recognized profession.

To ensure that individuals were trained in fields which meet national service delivery needs, NIMH began a major redirection of its clinical training activities in the mid 1970s with the result that today increasing numbers of trained personnel serve in public facilities, provide service to the chronically mentally ill, and are available to treat special population groups such as minorities, the aged, and children. The clinical training program has shaped and built the national training capacity to the point that the training community will continue to function productively without Federal support.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

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HEALTH CARE FINANCING ADMINISTRATION

Program Management

Of the funds made available under this head in Public Law 99-178, $9,401,000 are rescinded.

PROGRAM MANAGEMENT
Deferral/Rescission

Amounts Available for Obligation

1986 Appropriation	$ 1,265,739,000
1986 Sequester order	-54,433,000
Proposed rescission	-9,401,000
Subtotal, adjusted appropriation	1,201,905,000
Unobligated balance, start of year	
Total obligations	1,201,905,000

Summary of Changes

1986 Estimate	$ 1,265,739,000
1986 Sequester Order	-54,433,000
1986 Estimate After Sequestering	1,211,306,000
1986 Revised Estimate	1,201,905,000
Net change	-9,401,000

	1986 Base	Change from Base
Decreases:		
Program:		
1. Research demonstrations and evaluation projects	$ 29,332,000	$ -7,331,000
2. Medicare contractors	$ 922,069,000	$ -2,069,000

PROGRAM MANAGEMENT
Deferral/Rescission

Budget Authority by Activity

	1986 [1/] Appropriation	1986 After Sequestering	1986 [1/] Revised Estimate	Proposed Rescission
1. Research, demonstrations and evaluation projects ....BA	$ 16,000,000	$ 15,312,000	$ 14,400,000	$ 912,000
Obligations	(30,650,000)	(29,332,000)	(22,000,000)	(7,332,000)
2. Medicare contractors ....BA	-0-	-0-	-0-	-0-
Obligations	(963,500,000)	(922,069,000)	(920,000,000)	(2,069,000)
3. All other ....BA	73,533,000	70,371,000	70,371,000	-0-
Obligations	(271,589,000)	(259,905,000)	(259,905,000)	-0-
TOTAL ....BA	89,533,000	85,683,000	84,771,000	912,000
Obligations	(1,265,739,000)	(1,211,306,000)	(1,201,905,000)	(9,401,000)

[1/] Reflects withholdings of $350,000 in Research, Demonstrations, and Evaluation projects and $229,000 in Administrative Costs required by Section 515 of the conference version of the Treasury, Postal Service, and General Government Appropriation Act of 1986, included by reference in the full-year Continuing Resolution for 1986, P.L. 99-190.

PROGRAM MANAGEMENT
Deferral/Rescission

Budget Authority by Object

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
Full time permanents	$ 135,086,000	$ 134,409,000	$ 134,409,000	---
Other than FTP	3,675,000	3,675,000	3,675,000	---
Other compensation	2,077,000	2,077,000	2,077,000	---
Total personnel compensation	140,838,000	140,161,000	140,161,000	---
Benefits	18,385,000	18,297,000	18,297,000	---
Travel	5,323,000	3,992,000	3,992,000	---
Transportation	460,000	415,000	415,000	---
Rental payments to GSA	10,012,000	10,012,000	10,012,000	---
Rental payments	605,000	599,000	599,000	---
Commun., util., misc.	7,263,000	7,263,000	7,263,000	---
Printing & reproduction	5,900,000	5,200,000	5,200,000	---
Other services	1,049,323,000	1,000,198,000	996,021,000	$ -4,177,000
Supplies & materials	1,364,000	1,023,000	1,023,000	---
Equipment	3,229,000	2,421,000	2,421,000	---
Grants, subsidies & contrib.	23,037,000	21,725,000	16,501,000	-5,224,000
Total obligations	1,265,739,000	1,211,306,000	1,201,905,000	-9,401,000

PROGRAM MANAGEMENT
Deferral/Rescission

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
1. Research, Demonstrations and Evaluation projects	\$ 30,650,000 [1/]	\$ 29,332,000	\$22,000,000	\$7,332,000

[1/] Includes proposed reduction of \$350,000 required by Section 515 of the conference version of the Treasury, Postal Services, and General Government Appropriations Act of 1986, included by reference in the full-year Continuing Resolution for 1986, P.L. 99-190.

Purpose and Method of Operation

The Health Care Financing Administration's (HCFA) research, demonstration, and evaluation (RD&E) activities provide knowledge to enable the Administrator, the Secretary, the Congress and other interested parties to make informed and rational decisions regarding HCFA programs and policies.

For a substantial period of time, the costs of health care services have been increasing more rapidly than those of the general economy. This means that not only has the absolute number of dollars spent on health care increased rapidly, but also that the proportion of the Gross National Product related to health care has steadily increased. This long-range trend is, and has been, a matter of primary concern to HCFA as the leading purchaser of health care in the United States. Since the inception of HCFA, the overall purpose of the RD&E program has been to find ways to control this inflationary trend and to insure that every dollar was used effectively in the service of HCFA beneficiaries.

HCFA's existing research, demonstration, and evaluation activities include projects to test new reimbursement, coverage, eligibility, and program management approaches as well as research and evaluation studies of the impact of HCFA programs on health care costs, program expenditures, beneficiary access to health care services, the quality of care provided to beneficiaries, and the economics of the health care industry. HCFA is extensively involved in the creation of new and improved data sets to support these ongoing research and demonstration activities. These projects result in knowledge about the basic structure, incentives, costs, and effects of HCFA programs and policies and make it possible to refine existing policies, simulate or test various program changes on a trial basis, and develop innovative financing and delivery systems. Given the complexity of the issues involved, HCFA is continually striving to improve the rigor of its analyses by applying state of the art econometric, epidemiological, and evaluative techniques. This effort has required sophisticated in-house and extramural staff involvement.

Research on hospital classification and case-mix provided a basis for Medicare hospital reimbursement reform, beginning with refinements to routine per diem cost limits and leading to expanded total case limits. Finally, the RD&E investment provided the basis for the most significant program reform since the inception of the Medicare program--the Prospective

Payment System (PPS) based on a diagnosis-related groups (DRG) approach. Demonstration and evaluation activities proved the feasibility of this payment system in containing health care costs and developed tested methods to facilitate nationwide implementation. Initial results from implementation of this prospective payment system indicate that it will result in significant and ongoing savings to Medicare through its provision of financial incentives which encourage efficient health care delivery. A most important result is that the Medicare Hospital Trust Fund now appears solvent until the end of the century, at which time the aging of the population will place a new set of burdens on the Medicare program. The RD&E program is currently engaged in a major set of projects related to the evaluation, refinement, and extension of PPS.

HCFA's RD&E program has provided the basis for other program reforms such as risk-based payment for HMOs under Medicare extended coverage of cost-efficient providers such as ambulatory surgery centers and swing-beds in rural hosptials, and coverage of systems for community-based care as alternatives to expensive institutionalization. Without these RD&E activities, HCFA would not have the data base and factual experience necessary to develop successful legislative, policy, and program reform proposals related to PPS impact, refinement, and extensions to other areas.

Rationale for the Proposed Rescission

A rescission of $7,332,000 is proposed to restore funding to levels estimated in the President's Budget.

PROGRAM MANAGEMENT
Deferral/Rescission

Research, Demonstrations and Evaluation Projects

Impact Data

		1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
1.	Alternative Payment Systems	$ 6,451,996	$4,151,996	$2,300,000
	a. New Awards	3,050,000	750,000	$2,300,000
	b. Continuations Systems	3,401,996	3,401,996	--
2.	Hospital Payment Systems	6,579,959	5,679,959	900,000
	a. New Awards	1,855,016	955,016	900,000
	b. Continuations Systems	4,724,943	4,724,943	--
3.	Physician Payment Systems	1,078,756	1,078,756	--
	a. New Awards	--	--	--
	b. Continuations Systems	1,078,756	1,078,756	--
4.	State Programs for Long-Term Care	1,579,769	1,579,769	--
	a. New Awards	--	--	--
	b. Continuations Systems	1,579,769	1,579,769	--
	Program Analysis, Evaluation and Quality of Care[1]	11,233,023	7,101,023	4,132,000
	a. New Awards	4,056,156	1,327,156	2,729,000
	b. Continuations Systems	7,176,867	5,773,867	1,403,000
6.	Technology and Coverage	1,626,193	1,626,193	--
	a. New Awards	--	-	--
	b. Continuations Systems	1,626,193	1,626,193	--
7.	Beneficiary Awareness and Prevention	782,304	782,304	--
	a. New Awards	--	--	--
	b. Continuations Systems	782,304	782,304	--
Summary:				
	New Awards	8,961,172	3,032,172	5,929,000
	Continuations	20,370,828	18,967,828	1,403,000
	TOTAL PROGRAM	29,332,000[2]	22,000,000	7,332,000

[1] In the FY 1986 Congressional Budget submission, quality of care studies were associated with program area no.6, formerly entitled "Quality & Coverage." In FY 1987, quality of care has been combined with Program Analysis/Evaluation and Quality of Care, as these are closely related. In the above table, for comparability with FY 1987 figures, we have shifted the quality of care studies into program area no. 5.

Reflects a reduction of $350,000 as required by Section 515 of the conference version of the Treasury, Postal Service, and General Government Appropriation Act of 1986, included by reference in the full-year Continuing Resolution for 1986, P.L. 99-190.

PROGRAM MANAGEMENT
Deferral/Rescission

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
2. Medicare Contractors	$ 963,500,000	$922,069,000	$920,000,000	$2,069,000

Purpose and Method of Operation

The Medicare contractors carry out the government's responsibility of reimbursing Medicare beneficiaries and providers of service in a timely, accurate, and fiscally responsible manner. Our growing aging population and their respective need for medical services, compounded by inflation in the cost of health care, causes outlays for Medicare benefits to spiral. In FY 1986 outlays for Medicare's 32.3 million beneficiaries will be approximately 79.8 billion with an estimated workload of 342 million claims. HCFA has and will continue to implement policies designed to control cost through changes in reimbursment methodology and aggressive efforts to detect fraud and abuse. The Medicare contractors are at the core of this dynamic environment and play a vital role in the processing of Medicare claims and preserving the fiscal integrity of the trust funds.

The cost of administering the Medicare program will be $920,000,000 in FY 1986, 1.2 percent of total Medicare outlays. HCFA has successfully reduced the proportionate share of administrative costs while, at the same time, it has imposed greater demands on the Medicare contractors. These additional responsibilities resulted from changes in Medicare reimbursement policy, initiatives to reduce program expenditures, enhanced HCFA focus on new priorities, and an increase in claims workload.

Intermediaries are responsible for reimbursement to providers of services under Part A of the Medicare program. These responsibilities encompass receiving and accounting for Medicare benefit payments, auditing the financial records of providers, making final settlement of cost reports, recovering any Medicare overpayments, and safeguarding trust funds against payment for services that are not medically necessary. Significant changes have been made to the reimbursement methodology for inpatient hospital services. Under HCFA's Prospective Payment System (PPS), intermediaries reimburse hospitals for inpatient services based upon the number of Medicare beneficiaries in a Diagnosis Related Group (DRG) and the DRG rate for the primary diagnosis. The PPS replaces the cost per case limits created by the Tax Equity and Fiscal Responsibility Act (TEFRA). However, hospitals in those States which are exempt from PPS will continue to be reimbursed according to the provisions of the waiver.

Carriers are responsible for reimbursement to beneficiaries and providers of service under Part B of the Medicare program. These responsibilities include receiving and accounting for Medicare benefit payments, accounting for funds made directly to and/or on behalf of eligible Medicare beneficiaries, determining the allowable reasonable charge for a covered service that was medically necessary, computing and recovering overpayments if reimbursement was made erroneously, and establishing methodologies to identify aberrant utilization patterns which deviate from medically accepted norms and bringing such patterns to the attention of the appropriate professional groups.

Intermediaries and carriers provide information, guidance and technical support to both providers of service and beneficiaries on the administration of the Medicare program. Costs incurred by the intermediaries of $327.6 million and carriers of $592.4 million in fulfilling their respective responsibilities are reflected in the Medicare contractor budget request.

HCFA currently negotiates 91 contracts with intermediaries and carriers, including five experimental fixed price contracts. HCFA is responsible for monitoring all of these contractors' expenditures, tracking savings realized from payment safeguard activities and productivity investments, and reviewing contractor performance in paying claims, serving Medicare beneficiaries and assuring the fiscal integrity of the Medicare Trust Funds.

Rationale for the Proposed Rescission

A rescission of $2,069,000 is proposed to restore spending levels to those estimated to be appropriate in the President's Budget.

The proposed funding level of $920,000,000 reflects a continued emphasis on strengthening payment safeguards, including audit and medical review activities. The budget also reflects a strengthening of Medicare secondary payer efforts by contractors to ensure appropriate payment by liable third parties. Funding increases to strengthen some of these efforts are offset by continuing decreases in claims processing costs. The amount rescinded constitutes about .22 percent of the total cost for administering the Medicare program.

PROGRAM MANAGEMENT
Deferral/Rescission

Medicare Contractors

Impact Data

		1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
1.	Payment Safeguards			
	Medical Review/Utilization Review	$ 90,900,000	$ 90,900,000	
	Audit	103,900,000	103,900,000	
	Medicare Secondary Payer	28,000,000	28,000,000	
	Total, Payment Safeguards	$222,800,000	$222,800,000	
2.	Productivity Investments	$ 23,100,000	$ 23,100,000	
3.	Claims Processing			
	Claims Payment	$498,669,000	$496,600,000	$-2,069,000
	Reimbursement	24,000,000	24,000,000	
	Fixed-Price Contracts	57,200,000	57,200,000	
	Printing	3,100,000	3,100,000	
	Total, Claims Processing	$582,969,000	$580,900,000	
4.	Beneficiary and Provider Services			
	Hearing and Reconsiderations	$ 25,000,000	$ 25,000,000	
	Beneficiary Communications	57,000,000	57,000,000	
	Participating Physicians	11,200,000	11,200,000	
	Total Beneficiary Services	$ 93,200,000	$ 93,200,000	
Total Obligations		$922,069,000	$920,000,000	$-2,069,000
Contingency Fund		14,355,000	14,355,000	
	Total, Medicare Contractors	$936,424,000	$934,355,000	$-2,069,000

OFFICE OF HUMAN DEVELOPMENT SERVICES

HUMAN DEVELOPMENT SERVICES

FY 1986 Rescission Budget

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OFFICE OF HUMAN DEVELOPMENT SERVICES

Human Development Services

Of available funds under this head, $5,000,000 are rescinded from 1985 appropriations 1/ and $24,980,000 are rescinded from 1986 appropriations. 2/

Explanation of Language Changes

1/ This language will rescind the $5 million appropriated, but unobligated, in 1985 for Child Abuse Challenge grants. Funds are available in 1986.

2/ This language will reduce aging, developmental disabilities, Native Americans, and child abuse activities back to the 1986 President's Budget request levels.

Human Development Services

Amounts Available for Obligation

1986 Appropriation	$2,015,922,000
1986 Sequester order	-86,685,000
Proposed rescission	-24,980,000
Subtotal adjusted appropriated	1,904,257,000
Unobligated balance, start of year	11,968,000
Unobligated balance, end of year	-968,000
Unobligated balance lapsing	-423,000
Total obligations, adjusted	$1,914,834,000

Human Development Services

Summary of Changes

1986 Appropriation	$2,015,922,000
1986 Sequester order	-86,685,000
1986 Estimate after sequestering	1,929,237,000
1986 Section 515 withholding	-423,000
1986 After Sequestering and 515 withholding	1,928,814,000
1986 Revised estimate	1,903,834,000
Net change	$ -24,980,000

Program:	1986 Base	Change from Base
1. To return child abuse discretionary activities to the 1986 President's Budget request level........................	$13,339,000	- $3,296,000
2. To rescind a new categorical program for dependent care..........................	4,785,000	-4,785,000
3. To reduce research, training and discretionary projects related to aging to the 1986 President's Budget request.....	23,925,000	-11,425,000
4. To reduce funds for the developmentally disabled to the 1986 President's Budget request...................................	76,943,000	-3,943,000
5. To reduce training technical assistance, research and demonstration activities for Native Americans to the 1986 President's Budget request	1,616,000	-1,531,000
Net change, 1986................................		-24,980,000
Net change, 1985................................		-5,000,000 a/

a/ Proposal includes rescission of $5 million of Child Abuse Challenge grants appropriated, but unobligated in 1985.

Human Development Services

Budget Authority by Activity
(amounts in thousands)

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	1986 Proposed Rescission
1. Administration for Children, Youth and Families				
a. Child Abuse Challenge Grants	- - -	- - -	- - -	-5,000 a/
b. Child Abuse Discretionary Activities	$14,000	13,441	$10,043 b/	-3,296
c. Dependent Care...........	5,000	4,785	- - -	-4,785
2. Administration on Aging				
a. Research, Training, and Discretionary Projects....	25,000	23,925	12,500	-11,425
3. Administration on Developmental Disabilities				
a. State Grants................	53,400	51,104	50,250	- 854
b. Protection and Advocacy....	14,600	13,972	13,750	- 222
c. Special Projects............	2,800	2,680	- - -	-2,680
d. University Affiliated Facilities......	9,600	9,187	9,000	- 187
4. Administration for Native Americans				
a. Training and Technical Assistance.....	1,000	957	85	- 872
b. Research and Demonstration	700	670	- - - b/	- 659
5. All Other	1,889,822	1,808,559	1,808,249 b/	- - -
Total, Human Development Services-FY 1986 BA	2,015,922	1,929,237	1,903,834	-24,980
Total, Human Development Services-FY 1985 BA				- 5,000 a/
Total Funds Rescinded				-29,980

a/ Funds being rescinded were appropriated but unobligated in FY 1985. Funds had 2 year spending authority.

b/ Includes amount being withheld pursuant to section 515 of P.L. 99-190.

Human Development Services

Child Abuse Discretionary Activities

1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
$14,000,000	$13,441,000	$10,043,000 a/	-$3,296,000

a/ Includes $102,000 being withheld pursuant to Section 515 of P.L. 99-190

Purpose and Method of Operation - The purpose of the Child Abuse Discretionary program is to improve and increase national, State, community and family activities for the prevention, identification, and treatment of child abuse and neglect through research, demonstration, service improvement, information dissemination and technical assistance.

Research, demonstration and service improvement grants are awarded competitively to public and private nonprofit agencies, including State and local government agencies, universities and voluntary organizations. Grants and contracts are awarded on the basis of priority statements published in the Federal Register for grants and in the Commerce Business Daily for contracts. Contracts may be awarded to nonprofit or proprietary organizations. Projects supported by grants and contracts may run up to three years.

1981	$16,021,600
1982	9,479,000
1983	9,479,000
1984	9,489,000
1985	13,980,000

Rationale for Proposed Rescission - A rescission of $3,296,000 is proposed as a part of the President's overall budget reform plan to curtail Federal Government spending and thereby reduce the Federal deficit.

The proposed funding level of $10,043,000 will provide the following:

Program Data:

(in thousands)

Activity	Actual	Appropriation	After Sequestering	1986 Revised Estimate
Research, Demonstration and Service Improvement	$12,579	$13,326	$12,724	$9,394
Clearinghouse	617	498	498	473
Incidence	804	176	176	176
Total	$14,000	$14,000	$13,398	$10,043

Human Development Services

Dependent Care

1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
$5,000,000	$4,785,000	$ - - -	$4,785,000

Dependent Care Planning

Purpose and Method of Operations - The purpose of this new program is to provide States with funds for activities in two specific areas: activities related to dependent care resource and referral systems and activities related to school-age child care services. In each of these two areas, funds may be used to assist in the planning, development, establishment expansion or improvement of services but may not be used for costs of operation of any resource and referral center or before or after school child care program, make cash payments to intended recipients of services, subsidize direct provision of services, pay for construction or renovation or used as matching funds for Federal funds. Forty percent of funds must be used for activities related to dependent care resource and referral systems and sixty percent for activities related to school-age child care services.

Funds to support these activities are allotted to the States by formula. Each State shall receive an amount which bears the same ratio to the total amount appropriated as the population of the State bears to the population of all States except that no State will receive less than $50,000. The $50,000 minimum does not apply to the eligible Territories and Insular Areas.

Funding levels for the past two years have been:

1985	$ -0-
1986	$5,000,000*

*proposed for rescission

Rationale for the Proposed Rescission - This program is a newly authorized categorical program, funded for the first time in 1986. No awards have been made under this authority. A rescission of $4,785,000 is proposed for this program because similar activities can be carried out under other Federal funding sources, such as the $2.7 billion Social Services Block Grant and because many State and local programs addressing this area of concern currently exist. In order to help control Federal spending, it is proposed that this duplicative new categorical program not be implemented.

Human Development Services

Child Abuse Challenge Grants

1985 Appropriation	1985 Funds 1985 Obligations	Proposed Available in 1986	Rescission Of 1985 Funds
$5,000,000	- - -	$5,000,000	$5,000,000

Purpose and Method of Operations - The purpose of this program is to encourage States to establish and maintain trust funds or other funding mechanisms including direct State appropriations to support child abuse and neglect prevention activities.

Each State must make application for the funds to the Secretary at such time, in such manner, and containing such information as the Secretary deems essential but in any case must include: an agency to administer the funds, either the trust fund advisory board or, if lacking, the State liaison agency to the National Center on Child Abuse and Neglect; provision for keeping records and making such reasonable reports as the Secretary deems essential; and assurances that the funds will not be used to match other Federal funding.

Federal "matching" grants are to be the lesser of 25 percent of the total amount made available by the State in the previous year; or an amount equal to 50 cents times the number of children residing in such State according to the most current data available.

There are approximately 30 States with Children's Trust Funds.

Funding:

1985	$5,000,000*
1986	-0-

*proposed for rescission

Rationale for the Proposed Rescission - A rescission of $5,000,000 appropriated, but unobligated, in 1985 is requested. These funds are available in fiscal year 1986.

This is a newly authorized program for which no grants have been made. Over thirty States have begun trust funds with no financial incentive from the Federal Government. Other States are expected to do the same. Therefore, Federal support is not needed and in order to help control Federal spending, it is proposed that this new program not be implemented.

Human Development Services

Aging Research, Training and Discretionary Projects

1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
$25,000,000	$23,925,000	$12,500,000	$11,425,000

Purpose and Method of Operation - The purpose of the Training, Research, and Discretionary Program is to expand the Nation's knowledge and understanding of aging and the aging process, to design and test innovative ideas in programs and services for older individuals, and to help meet the needs for trained personnel in the field of aging through: (1) placing priority on the education and training or personnel to work with and on behalf of older individuals; (2) research and development of effective practices in the field of aging; and (3) dissemination of information on aging and the aging process acquired through such programs to public and private organizations or programs for older individuals.

Funding levels during the past five fiscal years have been as follows:

1981	$40,500,000
1982	$22,175,000
1983	$22,175,000
1984	$22,175,000
1985	$24,980,000

Rationale for the Proposed Rescission - A rescission of $11,425,000 is proposed for aging research and discretionary activities.

This rescission is consistent with long-standing Department policy of giving priority to service provision programs, and reducing programs that do not provide direct services.

Agency priorities can be met at the reduced funding level. Sufficient funds have been invested in these activities in prior years to assure that a level of $12,500,000 will fully support projects needed to provide information on the aging population.

Human Development Services

Developmental Disabilities State Grant Program

1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
$53,400,000	$51,104,000	$50,250,000	- $854,000

Purpose and Method of Operations - The Developmental Disabilities Program assists States in developing and implementing a comprehensive plan for meeting the needs of persons with developmental disabilities. Program emphasis is on ensuring that persons with developmental disabilities gave the range of services available to them which best promote self-sufficiency.

The funding level for the last five years for the Basic State Grant Program has been as follows:

1981	$42,145,000
1982	$41,453,000
1983	$43,180,000
1984	$43,750,000
1985	$50,250,000

Rationale for the Proposed Rescission - A rescission of $854,000 is proposed. This is the same level as the 1986 President's Budget request.

The proposed funding level of $50,250,000 is the same level as the 1985 appropriation. This level of funding will continue all of the types of services presently being provided.

Human Development Services

Developmental Disabilities Protection and Advocacy

1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
$14,600,000	$13,972,000	$13,750,000	- $222,000

Purpose and Method of Operations - The Protection and Advocacy Program is a State operated system to protect and advocate for the rights of persons with developmental disabilities.

The most common types of assistance were provided to persons with problems related to education, employment, transportation, vocational rehabilitation, medical services, abuse and neglect, housing, architectural barriers, and guardianship.

Rationale for the Proposed Rescission - A rescission of $222,000 is proposed as a part of the President's overall budget reform plan to curtail Federal Government spending and thereby reduce the Federal deficit.

The proposed funding level of $13,750,000 is the same level as the 1985 appropriation and the 1986 President's Budget request. After a 64% funding increase between 1984 and 1985, a funding level of $13,750,000 will be sufficient for protection and advocacy services in 1986. All of the types of services currently being provided will continue to be provided at service levels comparable to those supported in 1985.

Human Development Services

Developmental Disabilities Special Projects

1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
$2,800,000	$2,680,000	- - -	- $2,680,000

Purpose and Method of Operations - This program provides financial assistance for developing new technology and applying innovative methods to support the independence, productivity, and integration into the community of persons with developmental disabilities. Grants are awarded for demonstration, research, and evaluation projects which will expand or otherwise improve services to persons with developmental disabilities.

Rationale for the Proposed Rescission - A rescission of $2,680,000 is proposed for Special Projects.

This rescission is consistent with the long-standing Department policy to focus funds on direct services programs and reduce programs that do not provide direct services.

Human Development Services

Developmental Disabilities University Affiliated Facilites

1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
$9,600,000	$9,187,000	$9,000,000	-$187,000

Purpose and Method of Operations - This program provides operational and administrative support for a national network of University Affiliated Facilities and Satellite Centers. Grants are made annually to University Affiliated Facilities and Satellite Centers based upon satisfactory performance for interdisciplinary training, exemplary service and technical assistance demonstrations, and information dissemination activities.

The funding level for University Affiliated Facilities for the last five year has been as follows:

1981	$6,499,039
1982	$7,200,000
1983	$7,500,000
1984	$7,800,000
1985	$9,000,000

Rationale for the Proposed Rescission - A rescission of $187,000 is proposed for the University Affiliated Facilities.

The proposed funding level of $9,000,000 is the same as the 1985 appropriation and the 1986 President's Budget request. After funding increases since 1981, a funding level of $9 million in 1986 will be sufficient to support this program. All of the University Facilities and the Satellite Centers currently funded will continue to be supported at the request level.

Human Development Services

Native Americans - Training and Technical Assistance and Research, Demonstration and Evaluation

1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
$29,000,000	$27,753,000	$26,211,000 a/	-$1,531,000

a/ Includes withholding pursuant to Section 515, P.L. 99-190.

Purpose and Method of Operations - The purpose of training and technical assistance is to assist public and private Native American organizations in developing, conducting and administering projects to carry out locally determined social and economic development strategies. The funding mechanisms used by the Administration for Native Americans include grants, contracts for the procurement of training and technical assistance and interagency agreements.

The Administration for Native Americans provides technical assistance in a manner which enhances local decision-making and control to insure that local priorities and needs are addressed and a basis is provided for achieving self-sufficiency.

The research, demonstration, and evaluation program provides assistance to public and private agencies to test or assist in the development of new approaches and methods that will further the social and economic development of local Native American communities.

Funding levels for the last five years have been as follows:

1981*	$33,800,000
1982	$ 1,000,000
1983	$ 1,000,000
1984	$ 1,000,000
1985	$ 1,000,000

*In 1981 the Administration for Native Americans' appropriation was not made by separate line item. The amount shown represents all money appropriated.

Rationale for the Proposed Rescission - A rescission of $1,531,000 is proposed for these programs.

The rescission is consistent with the policy to reduce programs that do not provide services in order to maintain those programs that provide services.

OFFICE OF HUMAN DEVELOPMENT SERVICES

FAMILY SOCIAL SERVICES

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HUMAN DEVELOPMENT SERVICES

FAMILY SOCIAL SERVICES

Of available funds under this head, $6,157,000 are rescinded. 1/

Explanation of Language Change

1/ This language will reduce the 1986 appropriated amounts for Adoption Opportunities and Child Welfare Research and Development activities to the 1986 President's Budget request levels.

Family Social Services

Amounts Available for Obligation

1986 Appropriation	$777,237,000
1986 Sequester order	- 16,407,000
Proposed rescission	- 6,157,000
Subtotal, adjusted appropriation	$ 754,673,000
Unobligated balance lapsing	- 145,000
Total obligations, adjusted	$754,528,000

Family Social Services

Summary of Changes

1986 Appropriation	$777,237,000
1986 Sequester order	-16,407,000
1986 Estimate after sequestering	760,830,000
1986 Section 515 withholding	- 145,000
1986 Estimate after withholding	760,685,000
1986 Revised estimate	754,528,000
Net Change	-6,157,000

	1986 Base	Change from Base
Decreases:		
Program:		
1. To reduce Adoption Opportunities discretionary activities to the 1986 President's Budget request level in order to reduce Federal spending	$ 4,785,000	-$3,385,000
2. To reduce Child Welfare research and development activities to the 1986 President's Budget request level in order to reduce Federal spending	11,172,000	-2,772,000
Net Change		- 6,157,000

Family Social Services

Budget Authority by Activity

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	1986 Proposed Rescission
1. Adoption Opportunities.....	$5,000,000	$4,785,000	$1,400,000	-$3,385,000
2. Child Welfare, Research and Development.......	11,825,000	11,317,000	8,400,000 a/	-2,772,000
3. All Other.........	760,412,000	744,728,000	744,728,000	- - -
Total, Family Social Services	777,237,000	760,830,000	754,529,000 a/	-6,157,000

a/ Includes withholding of $145,000 pursuant to Section 515, P.L. 99-190

Budget Au hority Object

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	1986 Proposed Rescission
Grants, subsidies and contributions	$777,237,000	$760,830,000	$754,529,000	-$6,157,000

Family Social Services

Adoption Opportunities Program

1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
$5,000,000	$4,785,000	$1,400,000	-$3,385,000

Purpose and Method of Operations - The Adoption Opportunities program eliminates barriers to adoption and helps to find permanent homes for children who would benefit by adoption, particularly children with special needs. The three major program areas, as mandated by the legislation, are: (1) the development and implementation of a national adoption and foster care data gathering and analysis system; (2) the development and implementation of a national adoption information exchange system; and (3) the development and implementation of an adoption training and technical assistance program. Activities in these three areas are supported through grants and contracts.

Research and demonstration grants are awarded through competitive review to public and private non-profit agencies including State and local governments, universities and voluntary agencies. Contracts may be awarded to nonprofit or voluntary organizations. Grants and contracts are awarded on the basis of priority statements published in the Federal Register for grants and the Commerce Business Daily for contracts. Projects supported by grants and contracts generally run for one or two years. Past funding levels are as follows:

1981	$5,000,000
1982	1,912,000
1983	1,912,000
1984	1,912,000
1985	2,000,000

Rationale for the Proposed Rescission - A rescission of $3,385,000 is proposed for Adoption Opportunities.

In 1986, this program received an unneeded increase of $3 million over the 1985 level of $2 million. The revised amount of $1,400,000 is the same as the 1986 President's Budget request. This level will support the following:

Activity	1985 Actual	1986 Appropriation	1986 After Sequestering	198 Revised Estimate
Demonstration and Service Improvement	$1,800	$4,750	$4,535	$1,150
National Adoption Exchange	200	200	200	200
Adoption Compact	0	50	50	50
	$2,000	$5,000	$4,785	$1,400

Family Social Services

Child Welfare Research and Demonstration Activities

1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
$11,825,000	$11,317,000	$8,400,000 a/	-$2,772,000

a/ Includes funds being withheld pursuant to Section 515, P.L.99-190.

Purpose and Method of Operations - The Child Welfare Research and Demonstration program strenghtens the family as the primary agent responsible for the developmental needs of children, and youth. The Administration for Children, Youth and Families funds research, demonstration, dissemination, utilization and technical assistance activities in four basic areas -- child welfare, child care, youth development and child and family development. The resources budgeted for these four areas address the needs and problems confronting some of the most vulnerable children and families in the country: children in foster care, children in need of adoptive homes, children from poor families who require child care, and vulnerable youth who are runaways, homeless or at risk of deviant behavior. Grants are awarded competitively to public and private non-profit agencies including State and local governments, universities and voluntary agencies.

Rationale for the Proposed Rescission - A rescission of $2,772,000 is proposed for this program.

The request of $8,400,000 is the same level as the 1986 President's Budget request. This level will support the following:

Activity	1985 Actual	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate
Child Welfare	$7,200	$7,025	$6,754	$5,040
Child Care	480	480	408	336
Child and Family	4,200	4,200	4,053	2,940
Family and Youth	120	120	102	84
	$12,000	$11,825	$11,317	$8,400

OFFICE OF HUMAN DEVELOPMENT SERVICES

WORK INCENTIVES

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OFFICE OF HUMAN DEVELOPMENT SERVICES

Work Incentives

Of the funds made available under this head in Public Law 99-178, $46,884,000 are rescinded. 1/

Explanation of Language Change

1/ This rescission will eliminate new financing for the program in the last quarter of Fiscal Year 1986, with the program being phased out with unexpended carryover funds.

Work Incentives

Amounts Available for Obligation

1986 Appropriation	$220,000,000
1986 Sequester order	- 9,460,000
Proposed rescission	-45,884,000
Subtotal, adjusted appropriation	164,656,000
Total obligations	164,656,000

Work Incentives

Summary of Changes

1986 Estimate	$220,000,000
1986 Sequester order	- 9,460,000
1986 Estimate after sequestering	210,540,000
1986 Revised estimate	164,656,000
Net change	-45,884,000

	1986 Base Pos. (FTE)	1986 Base Amount	Change from Base Pos. (FTE)	Change from Base Amount
Increases:				
Program:				
1. Program direction and evaluation - to provide additional technical assistance support for the phase out of the Work Incentive Program	--	$782,000	---	+$429,000
Total increase.			---	+429,000
Decreases:				
Program:				
1. Grants-to-States - to eliminate new financing for program operations in the last quarter of Fiscal Year 1986	--	212,000,000	---	-45,884,000
2. Program direction and evaluation - to reflect reduced funding available for DOL Work Incentive Program staffing due to the proposed phase out of the program	60 (60)	3,427,000	-44 (-11)	-429,000
Total decrease.			-44 (-11)	-46,313,000
Total change...			-44 (-11)	-45,884,000

Work Incentives

Budget Authority by Activity

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	1986 Proposed Rescission
1. Grants to States....	$212,000,000	$202,884,000	$157,000,000	-$45,884,000
2. All other...	8,000,000	7,656,000	7,656,000	---
Total....	220,000,000	210,540,000	164,656,000	-45,884,000

Work Incentives

Budget Authority by Object

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	1936 Proposed Rescission
Total number of full-time permanent positions.............	90	90	46	-44
Total compensable work years: Full-time equivalent employment.	90	90	79	-11
Personnel compensation:				
Full-time permanent............	$3,351,000	$3,351,000	$3,003,000	-$348,000
Other than full-time permanent.	97,000	97,000	97,000	---
Other personnel compensation...	17,000	17,000	17,000	---
Total, personnel compensation..	3,465,000	3,465,000	3,117,000	-348,000
Personnel benefits...............	378,000	378,000	341,000	- 37,000
Travel & transportation of persons	288,000	288,000	288,000	---
Transportation of things.........	5,000	5,000	5,000	---
Rent, communications & utilities:				
Rental payments to GSA.........	238,000	238,000	194,000	- 44,000
Communications, utilities, and miscellaneous charges........	621,000	621,000	621,000	---
Printing and reproduction........	13,000	13,000	13,000	---
Other services...................	1,358,000	1,156,000	1,585,000	+429,000
Project contracts..............	1,574,000	1,432,000	1,432,000	---
Supplies and materials...........	20,000	20,000	20,000	---
Equipment........................	40,000	40,000	40,000	---
Grants, subsidies, and contributions...............	212,000,000	202,884,000	157,000,000	-45,884,000
Total budget authority by object..................	220,000,000	210,540,000	164,656,000	-45,884,000
(Consultant services)........	(---)	(---)	(---)	(---)
Related services)...........	(---)	(---)	(---)	(---)

Work Incentives

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
1. Grants to States.....	$212,000,000	$202,884,000	$157,000,000	-$45,884,000

Purpose and Method of Operation

To provide employment, training, and social services to recipients of and applicants for Aid to Families with Dependent Children (AFDC) who are required to register with the Work Incentive Program (WIN) to assist them into unsubsidized employment and ultimate self-sufficiency.

The Grants to States portion of the WIN appropriation is distributed to States by formula. WIN legislation requires that one-half of the employment and training funds be distributed to States based on the number of WIN registrants. The remainder of the funds is distributed on the basis of performance criteria which emphasize job placements and reductions in welfare payments. The legislation also requires that the allocations for States operating WIN Demonstration Programs be based on the States' "initial annual Fiscal Year 1981 allocation." The States' WIN Plan specifies the use of the funds to carry out the work registration requirement, and the other employment and social services necessary to help registrants attain unsubsidized employment. In addition, the State Plan documents the 10 percent State match required for the respective employment and social services costs.

Rationale for the Proposed Rescission

A rescission of $45,884,000 is proposed as part of the Administration's decision to phase out the WIN program, and the President's overall budget reform plan to curtail Federal spending. Studies of WIN have shown that it is not a cost-effective program. This rescission would eliminate new financing for the Work Incentive Program in the last quarter of Fiscal Year 1986. Alternative job-finding and social services programsare available for AFDC recipients under the Job Training Partnership Act (which requires equitable services to AFDC recipients), and the Social Services Block Grant.

	1986 Appropriation		1986 After Sequestering		1986 Revised Estimate		Proposed Rescission	
	FTE	Budget Authority	FTE	Budget Authority	FTE	Budget Authority	FTE	Budget Authority
2. Program direction & evaluation..	90	$8,000,000	90	$7,656,000	79	$7,656,000	-11	- 0 -

Purpose and Method of Operation

The program direction and evaluation (PD&E) activity provides Federal support necessary for overall program development, administration, and evaluation. Funding for this activity provides for the salaries and expenses for a total of 90 support positions in the Departments of Labor and Health and Human Services in both the National and Regional Offices, as well as contractual assistance and in-house services for program evaluation, technical assistance and training,and postage.

Rationale for the Proposed Rescission

A rescission is proposed which reduces funding for Department of Labor WIN salaries and expenses (S&E) by $429,000 and eliminates 11 authorized full-time equivalent employment (FTE's) associated with the reduced S&E financing. It is further proposed to use the recovered $429,000 within the PD&E activity for technical assistance to States for the phase out and grant closeout of the WIN program. The adjustment from one PD&E sub-activity to another would not change the overall PD&E budget authority level.

The Administration's decision to phase out the WIN program in Fiscal Year 1986 would necessitate that increased guidance be provided to States for program phase out and grant closeout, thereby eliminating some Federal staff responsibilities.

Work Incentives

Grants to States[1]

State or Outlying Area	1986[2]	1986 Revised	Proposed Rescission
Total	$202,884,000	$157,000,000	-$45,884,000
Alabama	1,877,000	1,453,000	-424,000
Alaska	537,000	416,000	-121,000
Arizona	1,427,000	1,104,000	-323,000
Arkansas	1,171,000	906,000	-265,000
California	27,791,000	21,506,000	-6.285,000
Colorado	3,003,000	2,324,000	-679,000
Connecticut	2,945,000	2,279,000	-666,000
Delaware	690,000	534,000	-156,000
Florida	3,065,000	2,370,000	-695,000
Georgia	3,346,000	2,590,000	-756,000
Hawaii	1,191,000	921,000	-270,000
Idaho	1,331,000	1,030,000	-301,000
Illinois	10,028,000	7,760,000	-2,268,000
Indiana	2,637,000	2,040,000	-597,000
Iowa	2,189,000	1,694,000	-495,000
Kansas	1,493,000	1,155,000	-338,000
Kentucky	2,001,000	1,549,000	-452,000
Louisiana	1,485,000	1,149,000	-336,000
Maine	1,141,000	883,000	-258,000
Maryland	3,838,000	2,970,000	-868,000
Massachusetts	6,688,000	5,175,000	-1,513,000
Michigan	14,621,000	11,314,000	-3,307,000
Minnesota	4,072,000	3,151,000	-921,000
Mississippi	1,545,000	1,195,000	-350,000
Missouri	2,879,000	2,228,000	-651,000
Montana	934,000	722,000	-212,000
Nebraska	701,000	543,000	-158,000
Nevada	590,000	456,000	-134,000
New Hampshire	419,000	324,000	-95,000
New Jersey	7,751,000	5,998,000	-1,753,000
New Mexico	845,000	654,000	-191,000
New York	17,534,000	13,569,000	-3,965,000
North Carolina	2,881,000	2,230,000	-651,000
North Dakota	454,000	352,000	-102,000
Ohio	11,297,000	8,742,000	-2,555,000

Work Incentives

Grants to States 1_/

State or Outlying Area	2_/ 1986	1986 Revised	Proposed Rescission
Oklahoma	$1,221,000	$945,000	-$276,000
Oregon	5,641,000	4,365,000	-1,276,000
Pennsylvania	9,209,000	7,127,000	-2,082,000
Rhode Island	1,153,000	892,000	-261,000
South Carolina	1,455,000	1,126,000	-329,000
South Dakota	870,000	673,000	-197,000
Tennessee	1,991,000	1,541,000	-450,000
Texas	4,194,000	3,246,000	-948,000
Utah	3,032,000	2,346,000	-686,000
Vermont	1,521,000	1,177,000	-344,000
Virginia	2,909,000	2,251,000	-658,000
Washington	8,742,000	6,765,000	-1,977,000
West Virginia	2,792,000	2,161,000	-631,000
Wisconsin	7,990,000	6,183,000	-1,807,000
Wyoming	317,000	245,000	-72,000
District of Columbia	1,853,000	1,434,000	-419,000
Puerto Rico	1,240,000	960,000	-280,000
Guam	151,000	117,000	-34,000
Virgin Islands	206,000	160,000	-46,000

1_/ Distribution is based on formula that requires one-half of the employment and training funds be distributed to States based on the number of WIN registrants. The remainder is distributed on the basis of performance criteria which emphasize job placements and reductions in welfare payments. Allocations for States operating WIN Demonstration Programs is based on the States' "initial annual Fiscal Year 1981 allocation."

2_/ Reflects a reduction of $9,116,000 pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985, P.L. 99-177.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF REFUGEE RESETTLEMENT

Refugee and Entrant Assistance

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OFFICE OF REFUGEE RESETTLEMENT

REFUGEE AND ENTRANT ASSISTANCE

Of available funds under this head, $87,551,000 are rescinded.

Refugee and Entrant Assistance

Amounts Available for Obligation

1986 Appropriation	$ 427,861,000
1986 Sequester order	-18,398,000
Proposed rescission	-87,551,000
Subtotal, adjusted appropriation	321,912,000
Unobligated balance, start of year	+3,196,000
Unobligated balance, end of year	---
Unobligated balance lapsing	- 100,000
Total obligations	325,008,000

Summary of Changes

1986 Estimate	$ 427,861,000
1986 Sequester order	-18,398,000
1986 Estimate after sequestering	409,463,000
1986 Revised estimate	321,912,000
Net change	-87,551,000

Decrease:	1986 Base	Change from base
Program:		
1. State-administered programs--social and supportive services reduced to a level consistent with the lower rate of recent arrivals	$ 327,730,000	$-23,815,000
2. Completion of targeted assistance programs; FY 1985 funds are sufficient to maintain services through mid-FY 1987	47,850,000	-47,850,000
3. Completion of education assistance	15,886,000	-15,886,000
Total decrease		-87,551,000

Refugee and Entrant Assistance

Budget Authority by Activity

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	1986 Proposed Rescission
1. State Administered Programs.	$342,456,000	$327,730,000	$303,915,000	$-23,815,000
2. Targeted Assistance.........	50,000,000	47,850,000	---	-47,850,000
3. Education Assistance for Children	16,600,000	15,886,000	---	-15,886,000
4. All Other...................	18,805,000	17,997,000	17,997,000	---
Total.....................	427,861,000	409,463,000	321,912,000	-87,551,000

Budget Authority by Object

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	1986 Proposed Rescission
All other object classes.......	$ 8,505,000	$ 8,139,000	$ 8,139,000	---
Grants, subsidies and contributions...............	419,356,000	401,324,000	313,773,000	$-87,551,000
Total, by object...............	427,861,000	409,463,000	321,912,000	-87,551,000

Refugee and Entrant Assistance

State Administered Programs

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	1986 Proposed Rescission
State Administered Programs				
Cash/Medical/Administration..	$270,756,000	$259,113,000	$259,113,000	---
Social Services..............	71,700,000	68,617,000	44,802,000	$-23,815,000
Total, State Administered Programs.....................	342,456,000	327,730,000	303,915,000	-23,815,000

Purpose and Method of Operations

To provide funding for a broad range of services to aid refugees in becoming adjusted to life in the United States as productive, non-dependent individuals. In this effort, States are funded to provide a program of supportive social services. Priority services are those which relate directly to rapid achievement of self-sufficiency: English language training and services specifically related to employment, such as employment counseling, job placement, and vocational training. Other allowable services include those contained in a State's program under Title XX of the Social Security Act and certain services identified in ORR policy instructions to the States, such as orientation and translation.

Rationale for the Proposed Rescission

A rescission of $23,815,000 is proposed. The funding of the refugee program by a series of Continuing Resolutions over the past three fiscal years has, in the face of declining refugee flows, resulted in maintaining social services funding at an artificially high level. At the proposed funding level of $44,802,000, those refugees most in need who have been in the country for less than three years will continue to receive appropriate services.

Refugee and Entrant Assistance

Targeted Assistance

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	1986 Proposed Rescission
Targeted Assistance..	$50,000,000	$47,850,000	---	$-47,850,000

Purpose and Method of Operations

This activity funded States for targeted assistance. Funds were used to assist refugee/entrant populations in areas where supplementation of available resources was necessary due to the short-term impact of a highly concentrated influx of refugees and entrants.

Rationale for the Proposed Recission

A rescission of $47,850,000 is proposed for targeted assistance activities. The program was initiated in FY 1982 as impact aid to areas which experienced a sudden influx of entrants in 1980. Further funding was provided from FY 1983 through FY 1985 as targeted assistance to areas where the number of refugees and entrants resettled from 1979 to 1981 temporarily exceeded local service capacity. These refugees and entrants have now been in the United States for five to eight years, and most are productive tax-paying members of their communities. The total appropriated through FY 1985 exceeded $200 million and will be adequate to continue assistance through March of 1987. Due to the lower and more stable arrival rates of recent years, the major problems of sudden and large local impact have been addressed, and normal social service allocations will be sufficient to meet current refugee service needs.

Refugee and Entrant Assistance

Education Assistance for Children

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	1986 Proposed Rescission
Education Assistance for Children.......	$16,600,000	$15,886,000	---	$-15,886,000

Purpose and Method of Operations

This activity provided grants to school districts with large numbers of refugee students. The grants helped the schools provide the initial special curriculum materials, bilingual teachers and aides, remedial classes, and guidance and counseling required to bring these students into the mainstream of the American education system. The program has been administered by the Department of Education via an interagency agreement with the Department of Health and Human Services.

Rationale for the Proposed Rescission

A rescission of $15,886,000 is proposed for this activity. Education assistance was initiated in FY 1980 to relieve local school districts of the initial cost of meeting special needs of refugee students. Since FY 1980, over $100 million has been appropriated and awarded for education assistance. The preponderance of current refugee resettlement is family reunification, thus incoming refugees are settling in communities which have been dealing with these children since 1975. Funds already appropriated have built the capacity (e.g., curricula, teacher training, etc.) necessary to meet the needs of refugee students, particularly since many refugees are now working and paying taxes to help support local school systems.

Refugee and Entrant Assistance

Summary State Table
(000)

STATE	1986*/	1986 REVISED	PROPOSED RESCISSION
TOTAL	$ 409,463	$ 321,912	$ 87,551
Alabama	746	590	156
Alaska	0	0	0
Arizona	2,923	2,635	288
Arkansas	400	306	94
California	153,739	125,288	28,451
Colorado	3,881	3,491	390
Connecticut	4,224	3,655	569
Delaware	46	18	28
Dist. of Columbia	6,734	6,605	129
Florida	24,659	2,732	21,927
Georgia	4,770	4,206	564
Guam	0	0	0
Hawaii	2,771	2,269	502
Idaho	995	876	119
Illinois	15,978	12,649	3,329
Indiana	665	542	123
Iowa	4,071	3,683	388
Kansas	3,838	2,922	916
Kentucky	652	493	159
Louisiana	2,944	2,085	859
Maine	1,192	1,025	167
Maryland	4,052	3,211	841
Massachusetts	18,823	16,057	2,766
Michigan	4,499	3,828	671
Minnesota	13,465	11,515	1,950
Mississippi	671	602	69
Missouri	1,960	1,625	335
Montana	248	213	35
Nebraska	676	554	122
Nevada	664	531	133
New Hampshire	532	465	67
New Jersey	4,998	3,640	1,358
New Mexico	463	411	52
New York	41,257	37,462	3,795
North Carolina	1,696	1,332	364

*/ Reflects a reduction of $18,398,000 pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985, Public Law 99-177.

Refugee and Entrant Assistance

Summary State Table
(000)

STATE	1986	1986 REVISED	PROPOSED RESCISSION
North Dakota	583	504	79
Ohio	4,641	3,887	754
Oklahoma	1,818	1,403	415
Oregon	10,389	8,828	1,561
Pennsylvania	8,125	6,175	1,950
Rhode Island	3,119	2,184	935
South Carolina	533	427	106
South Dakota	259	202	57
Tennessee	1,292	883	409
Texas	11,221	7,740	3,481
Utah	2,855	2,256	599
Vermont	574	532	42
Virginia	9,055	6,889	2,166
Washington	22,331	19,475	2,856
West Virginia	95	74	21
Wisconsin	3,241	2,864	377
Wyoming	100	73	27

COMMUNITY SERVICES PHASEOUT

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COMMUNITY SERVICES [BLOCK GRANT] PHASEOUT

Appropriation Language

Of the funds provided for the Community Services Block Grant Act for fiscal year 1986 in P. L. 99-178, $182,138,500 are rescinded.

COMMUNITY SERVICES PHASEOUT

Amounts Available for Obligation

1986 Appropriation..	$370,300,000
1986 Sequester order......................................	-15,923,000
1986 Proposed rescission.................................	-182,138,500
Subtotal, adjusted appropriation....................	$ 172,238,500
Unobligated balance, start of year....................	—
Total obligations....................................	$ 172,238,500

COMMUNITY SERVICES PHASEOUT

Summary of Changes

1986 Estimate..	$ 370,300,000
1986 Sequester order..................................	-15,923,000
1986 Estimate after sequestering......................	354,377,000
1986 Revised estimate.................................	-172,238,500
Net change....................................	-182,138,500

	1986 base	Change from base
Decreases:		
A. Program:		
1. Community services activities...........	350,262,000	-181,946,500
2. Federal administration block grants.....	$4,115,000	-$192,000
Net change............		-$182,138,500

COMMUNITY SERVICES PHASEOUT

Budget Authority by Activity

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	1986 Proposed Rescission
Community services activities............	$366,000,000	$350,262,000	$168,315,500	-$181,946,500
Federal administration block grants..........	4,300,000	4,115,000	3,923,000	-192,000
Total Budget Authority............	$370,300,000	$354,377,000	$172,238,500	-$182,138,500
FTE/Positions.........	57/57	57/57	57/57	0/0

COMMUNITY SERVICES PHASEOUT

Budget Authority by Object

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	1986 Proposed Rescisssion
Full-time equivalent of permanent positions........	54	54	54	---
Full-time equivalent of all other positions............	3	3	3	---
Total compensable workyears..................	57	57	57	---
Average ES salary...........	$63,765	$63,765	$63,765	---
Average GS grade............	11.66	11.66	11.66	---
Average GS salary...........	$44,652	$44,652	$44,652	---
Personnel compensation:				
Permanent positions.......	$2,794,000	$2,794,000	$2,730,000	-$64,000
Other personnel compensation............	45,000	45,000	45,000	---
Subtotal, personnel compensation..........	2,839,000	2,839,000	2,775,000	-64,000
Personnel benefits..........	295,000	295,000	285,000	-10,000
Benefits of former personnel	75,000	75,000	50,000	-25,000
Travel and transportation of persons................	121,000	121,000	118,000	-3,000
Transportation of things....	1,000	1,000	1,000	---
Rent, communications and utilities.................	151,000	151,000	151,000	---
Rental Payments to GSA......	264,000	264,000	264,000	---
Printing and reproduction...	35,000	35,000	15,000	-20,000
Other services..............	489,000	304,000	239,000	-65,000
Supplies and materials......	25,000	25,000	20,000	-5,000
Equipment...................	5,000	5,000	5,000	---
Grants, subsidies and contributions.............	366,000,000	350,262,000	168,315,500	-181,946,500
Total Budget Authority.....	$370,300,000	$354,377,000	$172,238,500	-$182,138,500

Community Services Activities

Community	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Services Activities..........	$366,000,000	$350,262,000	$168,315,500	-$181,946,500

Purpose and Method of Operation

This activity consists of two functions within the Community Services Block Grant (CSBG) program: (1) the provision of block grants to States to ameliorate the causes of poverty in communities within the States; and (2) a discretionary fund that provides for programs of regional and national significance designed to help poor persons. These include programs addressing areas of rural housing, economic development, special rural and urban needs, migrant and seasonal farmworkers assistance, and youth sports.

Each State requesting funds under the block grant program must certify in its application that the State agrees to provide: (1) a range of services and activities having a measurable and potentially major impact on causes of poverty in communities where poverty is an acute problem; and (2) activities designed to assist low-income participants, including the elderly.

Funds totalling $335,000,000 were allocated in 1985 for block grants to 50 States and the District of Columbia, Indian tribes, Puerto Rico, Guam, American Samoa, the Virgin Islands, the Northern Marianas and the Trust Territory of the Pacific Islands. Allocations were based on relative percentages of 1981 funding levels under Section 221 of the Economic Act of 1964. In 1985, OCS awarded 77 discretionary grants totalling $33,135,000 which included $6,130,000 for the national youth sports program; $19,920,000 for community economic development; $4,050,000 for rural housing and community facilities development; and $3,035,000 for migrant and seasonal farmworkers assistance.

Current FY 1986 funding plans for block grants to States are to award $167,500,000, or one half of $335,000,000, to cover the first and second quarters ending March 31, 1986. The reduction of $167,500,000 will include the sequester of $14,405,000 and the balance of $153,095,000 proposed for rescission. Of the total $31,000,000 appropriated for discretionary activities, $1,333,000 is included in the sequester order and $28,851,500 proposed for rescission, allowing a balance of $815,500 which has already been obligated for discretionary activities.

Rationale for the Proposed Rescission

The 1986 proposal to rescind $181,946,550 of the CSBG is based on considerations which would be persuasive even if there were no deficit problem. These considerations become even more compelling in the context of increasing deficits.

The rationale for rescission assumes that any domestic program not exempted under the Balanced Budget and Emergency Deficit Control Act of 1985 (Gramm-Rudman-Hollings) ought to be able to pass two tests: It must be unique, that is, non-duplicative of other programs and it must be an essential program. The CSBG program fails both tests.

The CSBG is duplicative of other programs in several ways. First, the 860 community action agencies (CAAs) which receive nearly 90% of the CSBG appropriation use a substantial portion of this money to help defray administrative costs incurred in delivering programs such as Head Start, weatherization, job training, etc., which are supported from other Federal funding sources. The National Community Action Foundation, which represents the CAA network, concedes as much as 40% of all CSBG funds are used of overhead costs, while the GAO has found cases where the use of CSBG funds for administration ranged up to 100%.

Second, the remaining portion of CSBG funds is largely used either to expand programs created under other Federal funding authorities, or to provide direct services to the poor which are similar to those funded under the $2.6 billion Social Services Block Grant (SSBG).

With respect to the use of the CSBG to help administer or expand other Federal programs, Congress, in authorizing and appropriating funds for these programs, did not assume a CSBG offset but provided sufficient funds to cover all costs, including those for administrative overhead and those for direct services. The use of two sources of Federal funds to deliver these programs is not only duplicative, but makes it extraordinarily difficult for State and Federal auditors to track the proper use of such funds, or to assess the impact of CSBG expenditures on CAA clients and services. The latter difficulty was noted by the GAO in its report on the CSBG issued in September, 1984.

Another reason for rescinding the CSBG is found in the fact that those CSBG funds which are not passed on to the States---roughly 9% of the total appropriation---are used for direct Federal grants to some 75-80 organizations operating projects in distressed areas that are no different from projects funded by such other Federal agencies as HUD, the Department of Agriculture, the Department of Labor, and the Environmental Protection Agency.

The CSBG is not only duplicative of other Federal programs, it is also a non-essential program. Its funding represents only a fraction---less than 1%---of the multibillion dollar programs, such as AFDC, food stamps, medicaid, etc., which make up the true social safety net and which Congress exempted from any reductions under Gramm-Rudman-Hollings in FY 1986. The CSBG is simply not an essential part of the social safety net and none of the safety net programs would be seriously affected by a rescission of the CSBG in FY 1986.

Not only is the CSBG not essential to the welfare of poor persons, it is not even needed for the survival of those community action agencies (CAAs) which have been performing effectively. This is evident from the fact that the CSBG accounts, on an average, for only 12% of CAA funding. The remaining 86%, or $2.4 billion of CAA funds--including money for salary and operating expenses---derives from other federal funding authorities, with

2% supplied by State and local governments and the private sector.
The above rationale is basically the same as that advanced in support of the proposal to terminate CSBG funding in FY 1987. A reason for not waiting until FY 1987 is furnished by the revised forecast of the Federal Budget deficit for FY 1986 announced on January 15, 1986 by OMB and CBO. According to the forecast, the deficit for FY 1986, after the cuts mandated by Gramm-Rudman-Hollings, is projected to be $209 billion, or $38 billion more than the target for FY 1986. To narrow this gap, it would make sense, therefore, to go beyond the $11.7 billion cuts mandated for FY 1986 and rescind all funding now for such non-essential programs as the CSBG.

Zero funding for the CSBG in the last two quarters of FY 1986 would not mean an immediate termination of all CAA activities funded from the CSBG. It is expected that CAAs will have approximately $50 million in carry-over funds which would permit an orderly phase-out, or transfer to alternate funding sources, of these activities. Effective CAAs ought to compete for Social Services Block Grant, Head Start, Low Income Home Energy Assistance, community development, job training, and other funding sources available to assist States in delivering social services. Thus, social services for the needy will continue to be supported.

Allocations to States for Community Services Block Grants a/

State or Outlying Area	1986 b/	1986 Revised	Proposed Rescission
TOTAL	$320,595,000	$167,500,000	-$153,195,000
Alabama	6,110,027	3,192,281	-2,917,746
Alaska	766,867	400,662	-366,205
American Samoa	209,194	109,297	-99,897
Arizona	2,710,597	1,416,195	-1,294,402
Arkansas	4,531,447	2,367,527	-2,163,920
California	29,723,271	15,529,399	-14,193,872
Colorado	2,899,371	1,514,823	-1,384,548
Connecticut	4,022,013	2,101,365	-1,920,648
Delaware	875,655	457,500	-418,155
Dist. of Columbia	5,474,843	2,860,420	-2,614,423
Florida	9,688,679	5,062,006	-4,626,673
Georgia	8,965,409	4,684,121	-4,281,288
Guam	197,985	103,441	-94,544
Hawaii	1,393,082	727,838	-665,244
Idaho	858,998	448,798	-410,200
Illinois	15,745,284	8,226,376	-7,518,908
Indiana	4,852,201	2,535,111	-2,317,090
Iowa	3,606,919	1,884,493	-1,722,426
Kansas	2,720,126	1,421,174	-1,298,952
Kentucky	5,619,497	2,935,996	-2,683,501
Louisiana	7,827,044	4,089,364	-3,737,680
Maine	1,750,003	914,317	-835,686
Maryland	4,572,327	2,388,885	-2,183,442
Massachusetts	8,308,176	4,340,740	-3,967,436
Michigan	12,346,166	6,450,452	-5,895,714
Minnesota	4,012,579	2,096,436	-1,916,143
Mississippi	5,291,029	2,764,383	-2,526,646
Missouri	9,223,270	4,818,845	-4,404,425
Montana	1,099,747	574,581	-525,166
Nebraska	2,321,469	1,212,889	-1,108,580
Nevada	872,633	455,921	-416,712
New Hampshire	902,516	471,534	-430,982
New Jersey	9,132,076	4,771,199	-4,360,877
New Mexico	1,841,757	962,256	-879,501
New York	28,924,280	15,111,954	-13,812,326

Allocations to States for
Community Services Block Grants (Continued)

State or Outlying Area	1986 b/	1986 Revised	Proposed Rescission
North Carolina	$ 8,721,116	$ 4,556,487	$ -4,164,629
North Dakota	820,676	428,776	-391,900
No. Mariana Islands	124,028	64,801	-59,227
Ohio	12,993,710	6,788,772	-6,204,938
Oklahoma	4,177,700	2,182,706	-1,994,994
Oregon	2,669,812	1,394,886	-1,274,926
Pennsylvania	14,113,208	7,373,672	-6,739,536
Puerto Rico	14,040,881	7,335,883	-6,704,998
Rhode Island	1,841,775	962,265	-879,510
South Carolina	5,121,757	2,675,944	-2,445,813
South Dakota	887,070	463,464	-423,606
Tennessee	6,569,183	3,432,175	-3,137,008
Texas	16,050,315	8,385,744	-7,664,571
Trust Terr. Pacific Islands	946,618	494,576	-452,042
Utah	1,267,539	662,246	-605,293
Vermont	933,962	487,964	-445,998
Virgin Islands	273,485	142,887	-130,598
Virginia	5,336,478	2,788,128	-2,548,350
Washington	3,941,406	2,059,251	-1,882,155
West Virginia	3,729,560	1,948,569	-1,780,991
Wisconsin	4,054,414	2,118,293	-1,936,121
Wyoming	875,655	457,500	-418,155
Indian Tribes Set Aside	1,708,115	892,432	-815,683

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a/ One half of one percent of the amount appropriated for each fiscal year is apportioned on the basis of need among Guam, American Samoa, the Virgin Islands, the Northern Mariana Islands and the Trust Territory of the Pacific Islands. After this apportionment and such amount as is determined necessary for discretionary purposes (not to exceed 9%) the Secretary allots to each State an amount which bears the same ratio to such remaining amount as the amount received by the State for Fiscal Year 1981 under section 221 of the Economic Opportunity Act of 1964 bore to the total amount received by all States for Fiscal Year 1981 except that no State receives less than one-quarter of one percent of the amount appropriated. (Puerto Rico and the District of Columbia are deemed to be States for allocation purposes).

b/ Reflects a reduction of $14,405,000 pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985, P.L. 99-177.

Federal Administration - Community Services Activities

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
Program Administration...	$4,300,000	$4,115,000	$3,923,000	-$192,000

Purpose and Method of Operation

This activity provides for salaries and expenses of staff to administer the Community Services Block Grant appropriation including direct block grants to States, Indian grants and discretionary projects in the areas of economic development, rural community facilities, migrants and seasonal farmworkers, and national youth sports.

Rationale for the Proposed Rescission

The proposed rescission of $192,000 are reductions in administrative expenses associated with the proposed program rescissions, such as costs for independent reviews of discretionary grant applications performed by individuals outside the Federal work-force, elimination of need for data collection of block grant activities, and other administrative overhead expenses shown in the table below.

Personnel compensation and benefits...	$3,134,000	$3,134,000	$3,060,000	$ -74,000
Benefits to former personnel...........	75,000	75,000	50,000	-25,000
Travel and transportation...........	122,000	122,000	119,000	-3,000
Rental payments to GSA.................	264,000	264,000	264,000	---
Rent, communications and utilities.......	151,000	151,000	151,000	---
Printing and reproduction.............	35,000	35,000	15,000	-20,000
Other services.......	489,000	304,000	239,000	-65,000
Supplies and materials	25,000	25,000	20,000	-5,000
Equipment............	5,000	5,000	5,000	---
Totals............	$4,300,000	$4,115,000	$3,923,000	$ -192,000

Community Development Credit Union Revolving Fund

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
CDCU:				
Budget Authority	$ ---	$ ---	$ ---	$ ---
Unobligated Funds	2,528,562	2,528,562	---	-2,528,562

Purpose and Method of Operation

The Community Development Credit Union Loan Fund (CDCU) is a revolving fund originally established under the Economic Opportunity Act of 1964 and continued under the Community Economic Development Act of 1981.

Rationale for the Proposed Rescission

The budget estimates request no new direct loans or loan guarantees from the CDCU in 1986. The remaining balance of this revolving fund as of September 30, 1985, was $2,528,562. This balance is proposed for rescission and return to U. S. Treasuary general fund.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEPARTMENTAL MANAGEMENT

FY 1986 Rescissions

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

General Departmental Management

Of the funds made available under this head in P.L. 99-178, $19,619,000 are rescinded.

General Departmental Management

Amounts Available for Obligation

1986 Appropriation	$144,449,000
1986 Sequester order	-6,211,000
Proposed rescission	-19,619,000
Subtotal, adjusted budget authority	118,619,000
Receipts and reimbursements from:	
Trust funds	+8,000,000
1986 Sequester order	-344,000
Subtotal, adjusted reimbursements	+7,656,000
Total, adjusted amounts available for obligation	$126,275,000

Summary of Changes

1986 Estimate	$144,449,000
1986 Sequester order	-6,211,000
1986 Estimate after sequestering	138,238,000
1986 Revised estimate	118,619,000
Net change	-19,619,000

Decreases:	1986 base	Change from base
Program:		
1. AIDs demonstrations - support for four projects demonstrating the delivery of health care services to victims of acquired immune deficiency syndrome will be eliminated	$15,312,000	-$15,312,000
2. Cancer construction - support for new construction of the Mary Babb Randolph Cancer Center in West Virginia will be eliminated	4,307,000	-4,307,000
Total, decreases		-$19,619,000

General Departmental Management

Budget Authority by Activity

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	1986 Proposed Rescission
1. AIDS demonstration projects.........	$ 16,000,000	$ 15,312,000	---	-$15,312,000
2. Cancer center construction A/..	4,500,000	4,307,000	---	-4,307,000
3. All other.........	131,949,000	126,275,000	126,275,000	---
Subtotal, obligations......	$152,449,000	145,894,000	126,275,000	-$19,619,000
Less: trust fund transfers........	-8,000,000	-7,656,000	-7,656,000	---
Total, budget authority........	$144,449,000	$138,238,000	$118,619,000	-$19,619,000

A/ FY 1986 Appropriation Act required that $4,500,000 of amounts available to the National Cancer Institute shall be transferred to GDM for construction of the Mary Babb Randolph Cancer Center in West Virginia.

Budget Authority by Object

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	1986 Proposed Rescission
Lands and structures..	$4,5000,000	$4,307,000	---	-$4,307,000
Grants, subsidies and contributions....	20,500,000	19,619,000	---	-19,619,000
Other objects.........	131,949,000	126,275,000	126,275,000	---
Total, by object..	$152,449,000	$145,894,000	$126,275,000	-$19,619,000

General Departmental Management

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	Proposed Rescission
1. AIDS demonstration projects.........	$16,000,000	$15,312,000	—	$15,312,000

Propose and Method of Operation

This new program, established under the FY 1986 appropriation, is intended to provide grant awards to assist victims of Acquired Immune Deficiency Syndrome (AIDS). The $16,000,000 appropriation was intended to fund four projects designed to demonstrate the delivery of health care services to AIDS victims. Projects would be conducted by entities located, and providing services to persons residing, in those four standard metropolitan statistical areas having the highest concentration of persons suffering from AIDS. Grant awards would be made under authority of section 301 of the Public Health Service Act.

Rationale for the Proposed Rescission

The $15,312,000 rescission is proposed as part of the President's overall budget reform plan to curtail Federal spending and to not begin new programs. These demonstrations are in excess of Departmental needs. Moreover, the Department opposes these demonstrations since a comprehensive research effort is already being done in HHS.

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	Proposed Rescission
2. Cancer construction..	$4,500,000	$4,307,000	—	-$4,307,000

Purpose and Method of Operation

Assistance would be provided to permit the construction of the Mary Babb Randolph Cancer Center in West Virginia. Under the terms of the FY 1986 HHS Appropriation Act, $4,500,000 available to the National Cancer Institute (reduced to $4,307,000 under sequesteration) shall be transferred to General Departmental Management (the Office of the Secretary) this year. An award would then be made for construction of the Randolph Center under the contract provisions of section 301(a)(7) of the Public Health Service Act.

Rationale for the Proposed Rescission

The $4,307,000 rescission is part of the President's overall budget reform plan to curtail Federal spending. The rescission proposal is also consistent with the Department's budget policies to eliminate all unnecessary construction.

Moreover, this particular project failed to meet the review criteria of the National Cancer Advisory Board and was disapproved for funding consideration. The Administration believes that if funds are made available for construction, then they should be used for the most meritorious projects that gain approval under a competitive process.

DEPARTMENTAL MANAGEMENT

Policy Research

Of the funds made available under this head in P.L. 99-178, $220,000 are rescinded.

Policy Research

Amounts Available for Obligation

1986 Appropriation..	$6,500,000
1986 Sequester order......................................	-280,000
Proposed rescission.......................................	-220,000
Total, adjusted appropriation.............................	$6,000,000

Summary of Changes

1986 Estimate...	$6,500,000
1986 Sequester order......................................	-280,000
1986 Estimate after sequestering..........................	6,220,000
1986 Revised estimate.....................................	6,000,000
Net Change..	-220,000

	1986 base	Change from base
Decreases:		
Program:		
1. Policy research program—	$6,220,000	-$220,000
Rescission would reduce the funds available for the Multi-Regional Policy Impact Simulation (MRPIS) project....	($478,000)	(-$220,000)

Budget Authority by Object

	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	1986 Proposed Rescission
Grants, subsidies and contributions....	$3,011,000	$2,731,000	$2,511,000	-$220,000
Other objects.........	3,489,000	3,489,000	3,489,000	---
Total, by object....	$6,500,000	$6,000,000	$6,000,000	-$220,000

Policy Research

	1986 Appropriation	1986 After Sequestering	1986 Revised Estimated	Proposed Rescission
1. Policy research program.........	$6,500,000	$6,220,000	$6,000,000	-$220,000

Purpose and Method of Operation

Through grant and contract assistance, this program conducts research and demonstrations aimed at three broad objectives: (1) provide policy-relevant information on national trends concerning public and private human resource activities to identify emerging policy problems and potential solutions, (2) provide specific data to develop and assess the impact of new potential public sector policy proposals, in particular their costs and benefits, and (3) provide information for the development of Administration strategies to influence private sector activities.

Within the Policy Research, the FY 1986 appropriation added $500,000 to be used for the Multi-Regional Policy Impact Simulation (MRPIS) model project. The $500,000 would provide additional funding for continuing development and operation of the MRPIS model. However, the $500,000 available for MRPIS will be reduced to $478,000 under sequestering in FY 1986. The Department plans to request a reprogramming of the $258,000 remaining funds available under the appropriation after this rescission for MRPIS in order to fund more relevant projects.

Rationale for the Proposed Rescission

The $220,000 rescission is proposed as part of the President's overall budget reform plan to control Federal spending. Together with the sequestration required by the Balanced Budget and Emergency Deficit Reduction Act, the rescission would reduce the Policy Research funding level to the amount requested by the President in the FY 1986 budget. The added funds are unnecessary, particularly as they were added to fund a specific project by a specific grantee—the MRPIS model. This model is of little utility to HHS as it produces information on broad regional economic impacts, not on the populations or activities of principal concern to the Department—health care, income security and social services for the elderly, disabled and poor.

General Provisions

Sec. ____. Section 202 of the Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriation Act, 1986, is amended by striking out "no fewer than 6,100 new and competing research projects" and inserting in lieu thereof "the maximum number of new and competing research projects as the Secretary of Health and Human Services determines in light of appropriations available for fiscal year 1986, would maximize scientific progress and enhance stabilization of the science base".

Explanation of Change:

This language change is needed in order to provide the National Institutes of Health sufficient managerial flexibility to award individual research project grants at a level consistent with peer review recommendations and good management practice. The new language will allow NIH to individually negotiate each award to maximize research progress under the grant, and reaffirms the importance of providing stability to the science base over the long run.

Report on Sequestration Under the Balanced Budget and Emergency Deficit Control Act of 1985 (Gramm-Rudman-Hollings) for Committee on Appropriations

1986

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FISCAL YEAR 1986 REPORT ON SEQUESTRATION

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

Salaries and Expenses

Effect of Sequestration

FY 1986 Funding Level	Sequestration (-)	FY 1986 Available After Sequestration
$394,573,000	$16,967,000	$377,606,000

Effect of Sequestration

FDA will achieve the required sequestration reductions through a combination of decreases in operating expenses and restrictions on hiring and overtime. Because FDA is a personnel-intensive agency, with two-thirds of its budget going directly for personnel salaries and benefits, reductions greater than 4.3% must be made in other operating expenses in order to avoid Reductions-In-Force (RIFs) or furloughs.

Overall travel costs will be reduced by 16 percent, although travel for inspections will be maintained at current levels at the expense of travel support for other activities. Printing costs will be decreased by 17 percent, although efforts will be made to ensure that publications in direct support of regulatory efforts will be maintained. Funding for supplies and equipment will be reduced by 18 percent and 41 percent, respectively. Necessary deferrals in purchasing new and replacement scientific equipment may affect the agency's ability to keep its scientific capabilities current with the most recent technological developments.

Extramural contracts and grants, which comprise only 3 percent of the agency's budget, will be reduced by 36 percent, requiring a reduction in support of State contracts to supplement FDA inspections and the elimination of certain research contracts and grants. However, as directed by Congress, grants for Orphan Products Development will not be reduced more than 4.3 percent, meaning that other research efforts providing FDA with outside expertise will absorb greater reductions or be curtailed.

In the area of personnel expenses, FDA will impose hiring restrictions. Exceptions will be made, however, to provide relief to a few critical program activities, such as AIDS prevention and treatment research, new drug and medical device evaluations, and implementation of the recent generic drug legislation.

Overall, the agency expects to avoid RIFs and furloughs, but FDA will instead need to significantly reduce the level of operating support it provides its employees, as well as curtail extramural efforts in areas such as collecting experience data on regulated products and contracting with States to supplement FDA inspection activities. While the agency will attempt to protect certain activities from the full effect of the mandatory sequestration reductions, all FDA programs will likely feel, to a certain degree, some effect of the reductions.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

Standard Level User Charges

Effect of Sequestration

FY 1986 Funding Level	Sequestration (-)	FY 1986 Available After Sequestration
$25,733,000	$1,106,000	$24,627,000

Effect of Sequestration

To accommodate the sequestered reduction in the Standard Level User Charges (SLUC) appropriation account and to avoid an anti-deficiency situation, FDA will use the authority in its Appropriation Act to transfer $1.1 million from the Salaries and Expenses account to the SLUC account. Reducing SLUC payments to the General Services Administration (GSA) requires actual space reductions, since GSA has not adjusted SLUC rates downward to the agencies for 1986 as a result of scheduled sequestrations. However, the moves and renovations necessary to reduce space and consolidate activities are costly, and FDA has no funds to cover such expenses. In addition, because nearly one-half of the fiscal year has passed, GSA would not be able to accomplish such renovations this year. Further, such consolidations and renovations are not required by the President's 1987 budget request. Therefore, funds will be transferred from the Salaries and Expenses account to cover these payments in 1986.

FDA201/PHS2

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

Buildings and Facilities

Effect of Sequestration

FY 1986 Funding Level	Sequestration (-)	FY 1986 Available After Sequestration
$1,441,000	$62,000	$1,379,000

Effect of Sequestration

As a result of sequestration, some minor repair and improvement work on facilities will be deferred. In general, though, the Agency will seek to reduce the scope of the projects requested to accomplish them within the reduced funding level.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

Revolving Fund for Certification and Other Services

Effect of Sequestration

FY 1986 Funding Level	Sequestration (-)	FY 1986 Available After Sequestration
$2,624,000 1/	$113,000	$2,511,000

Effect of Sequestration

As a result of sequestration, every effort will be made to minimize the reduction of color additive and insulin certification services by reducing expenditures for travel and the purchase of equipment and supplies.

1/ This amount represents the anticipated spending level. This account has no formal appropriation.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Bureau of Health Care Delivery and Assistance

Effect of Sequestration

Maternal and child health block grant	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
	$478,000,000	-$20,554,000	$457,446,000

Effect of Sequestration

The sequestration will reduce the amount available for Grants to States by $17,470,900 to $388,829,100 and will reduce the set-aside amount for Special Projects of Regional or National Significance (SPRANS) by $3,083,100 to $68,616,900. The level of funding for Hemophilia projects and for all other categories of SPRANS grants will be reduced by 4.3%. The number of awards will decline from 420 in FY 1985 to 384 in FY 1986.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Bureau of Health Care Delivery and Assistance

Effect of Sequestration

Community health centers	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
	$400,000,000	-$4,000,000	$396,000,000

Effect of Sequestration

The sequestration of 1 percent of the program's funds will reduce funds available for the expansion of services in rural and urban areas. Funds targeted for use in approximately 10 communities will be eliminated. These expansions would have provided services, at capacity, to 50,000 residents of underserved areas.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Bureau of Health Care Delivery and Assistance

Effect of Sequestration

Black lung clinics	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
	$3,400,000	-$146,000	$3,254,000

Effect of Sequestration

The sequestration of 4.3 percent of the program's funds would reduce the funds available to cover the costs of certain ancillary services such as outreach and health related services that are not reimbursable under public and private health insurance packages. The number of black lung clinics (38) providing care to 47,500 victims of black lung disease is not affected by the sequestration.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Bureau of Health Care Delivery and Assistance

Effect of Sequestration

Migrant health	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
	$45,400,000	-$454,000	$44,946,000

Effect of Sequestration

The sequestration would reduce the funds available to cover increased salary, malpractice insurance, supplies, equipment and other operating costs. Reductions in the scope of services available in all migrant projects will be made in order to maintain basic primary medical services.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Bureau of Health Care Delivery and Assistance

Effect of Sequestration

Family Planning	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
	$142,500,000	-$6,128,000	$136,372,000

Effect of Sequestration

The reduction of funds affecting grants for family planning services will be partially offset by the enhanced generation of program income through realistic and appropriate fee schedules for clients at clinic sites. Additionally, other efforts that have been undertaken during this past year will lead to more efficient operations, which in turn will mitigate some of the impact of the funding reduction on all program areas. These efforts include: increased communication and coordination between the Regional Health Administrators and the DASPA; increased use of technical assistance in streamlining clinic operations, and more effective oversight by Headquarters staff of all phases of the program's operation.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Bureau of Health Care Delivery and Assistance

Effect of Sequestration

Home health services	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
	$1,500,000	-$65,000	$1,435,000

Effect of Sequestration

The sequestration of 4.3 percent of the program's funds would reduce the number of grants and loans by two (2), from about 32 to about 30.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Bureau of Health Care Delivery and Assistance

Effect of Sequestration

National health service corps	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
	$58,500,000	-$2,516,000	$55,984,000

Effect of Sequestration

The sequestration of 4.3 percent of the program's funds will result in a reduction of the amount that would be available for reprogramming to the Community Health Center (CHC) program in support of about 62 NHSC obligors placed and fulfilling their service obligation in community health centers under the Private Placement Assignment (PPA) initiative in FY 1986. In addition, $43,000 would be sequestered from the $500,000 available to make Community Site Loans in FY 1986.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Bureau of Health Care Delivery and Assistance

Effect of Sequestration

National health service corps scholarships	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
	$2,300,000	-$99,000	$2,201,000

Effect of Sequestration

The sequestering would result in a reduction of 2 or 3 scholarship awards made to former recipients of the Exceptional Financial Need Scholarship program to fund the remainder of their medical/dental education. Approximately 39 awards would be made with the remaining funds.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Bureau of Health Care Delivery and Assistance

Effect of Sequestration

Hansen's disease center	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
	$19,103,000	-$821,000	$18,282,000

Effect of Sequestration

The sequestration would be absorbed through reductions in the Contract Care Program. Contracts will be written to reflect actual usage rates during the previous two years, travel will be restricted, a stricter drug procurement policy will be implemented, and the clinical field study program will be elimiriated. The level of services to patients will not be materially affected in FY 1986.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Bureau of Health Care Delivery and Assistance

Effect of Sequestration

Payment to Hawaii	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
	$3,300,000	-$142,000	$3,158,000

Effect of Sequestration

The sequestration will result in a reduction of the Federal government's support of Hawaii's Hansen's disease program from 82 percent to 79 percent of patient care costs, compared to 66 percent in FY 1985.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Bureau of Health Care Delivery and Assistance

Effect of Sequestration

BHCDA, Direct operations	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
	$44,289,000	-$1,904,000	$42,385,000

Effect of Sequestration

The sequestration would result in the support of about 37 fewer FTEs. In addition, travel will be reduced by about 5 percent, training by about 40 percent, and equipment by more than 50 percent. The ability of the Bureau of Health Care Delivery and Assistance to operate and monitor its programs would not be severely affected.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Program Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
H.P Student Assistance Exceptional financial need scholarships......	$7,000,000	-$301,000	$6,699,000

Effect of Sequestration

The sequestration will reduce the amount available for the exceptional financial need scholarships program to $6,699,000. This will support approximately 391 recipients who are in their first year of post-baccalaurate study, with an average scholarship award of $17,111. This is a reduction of approximately 18 recipients from the FY 1986 Appropriation level out of 409 recipients.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Program Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
H.P. Institutional Assistance			
Advanced Financial Distress........	$4,100,000	-$176,000	$3,924,000
Two-Year Medical and Osteopathy School..........	500,000	-21,000	479,000
Total.........	$4,600,000	-$197,000	$4,403,000

Effect of Sequestration

The sequestration will reduce the amount available for the advanced financial distress program to $3,924,000. This will support four traditionally black schools (Meharry Medical and Dental Schools, Xavier and Tuskegee) in their fifth year of funding under a revised plan to achieve financial solvency. The reduction of $176,000 will not result in a significant impact to the schools.

The sequestration will reduce the amount available for the two-year medical and osteopathy schools to $479,000. This will support an estimated 2 projects for financial assistance to maintain or improve those schools. This is the same number of projects as supported under the FY 1986 Appropriation level but at a reduced level.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Program Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Health Promotion/Disease Prevention			
Public Health Capitation..........	$ 5,000,000	-$215,000	$ 4,785,000
Health Administration Grants..............	1,500,000	- 64,000	1,436,000
Public Health Traineeships........	3,000,000	- 129,000	2,871,000
Health Administration Traineeships........	500,000	- 21,000	479,000
Preventive Medicine Residencies.........	1,600,000	- 69,000	1,531,000
Total..............	$11,600,000	-$498,000	$11,102,000

Effect of Sequestration

The sequestration will reduce the amount available for the public health capitation program to $4,785,000. This will support 23 schools of public health with a participating enrollment of approximately 7,300 students, providing approximately $655 per student. This is the same as the FY 1986 Appropriation level, however $30 less per student.

The sequestration will reduce the amount available for the health administration grants to $1,436,000. This will provide approximately 30 awards benefitting approximately 2,250 students. This is $2,000 less per project or a reduction of 4% as would be awarded under the FY 1986 Appropriation level.

The sequestration will reduce the amount available for the public health traineeship program to $2,871,000. This will provide 23 formula grant awards to schools of public health which will be distributed to approximately 1,444 trainees. This is a reduction of approximately 252 trainees or 14.8% from the FY 1986 Appropriation level.

The sequestration will reduce the amount available for the health administration traineeship program to $479,000. This will support approximately 33 grant awards assisting an estimated 358 trainees providing approximately $1,333 per trainee. This is a reduction of approximately 17 trainees or 4.5% from the FY 1986 Appropriation level.

The sequestration will reduce the amount available for the preventive medicine residencies program to $1,531,000. This will provide support for approximately 13 projects benefitting approximately 148 residents. This is a reduction of 1 project (7.1%) and 12 residents (7.5%) from the FY 1986 Appropriation level.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Program Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Primary Care Support Program			
Family Medicine and General Dentistry Residencies and Training..............	$36,000,000	-$1,548,000	$34,452,000
General Internial Medicine and Pediatrics............	18,500,000	- 796,000	17,704,000
Family Medicine Departments...........	7,000,000	- 301,000	6,699,000
Physician Assistants...	4,800,000	- 206,000	4,594,000
TOTAL..............	$66,300,000	-$2,851,000	$63,449,000

Effect of Sequestration

The sequestration will reduce the amount available for the family medicine and general dentistry residencies program to $34,452,000. This will provide support for approximately 280 family medicine projects supporting 20,127 residents, trainees and faculty. This is a reduction of 14 family medicine projects or 4.8% and 1,012 residents, trainees and faculty supported or 4.8% from the FY 1986 Appropriation level. The general dentistry residency program will support 33 projects assisting 145 first-year students. This is a reduction of 2 general dentistry residency programs or 5.7% and 10 first-year students or 6.4% from the FY 1986 Appropriation level.

The sequestration will reduce the amount available for the general internal medicine and pediatrics program to $17,704,000. This will provide support for approximately 96 projects supporting approximately 1,554 residents and faculty. This is a reduction of 2 projects or 2% and 42 residents and faculty or 2.6% from the FY 1986 Appropriation level.

The sequestration will reduce the amount available for the family medicine department program to $6,699,000. This will provide support for approximately 67 projects supporting an estimated 12,730 residents and faculty. This is a reduction of 3 projects or 4.3% and 570 residents and faculty or 4.3% from the FY 1986 Appropriation level.

The sequestration will reduce the amount available for the physician assistants program to $4,594,000. This will support approximately 44 projects benefitting about 1,876 students. This is a reduction of 1 project or 2.2% and 43 students or 2.2% from the FY 1986 Appropriation.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Program Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Health Professions Educational Initiatives..........	$8,000,000	-344,000	$7,656,000

Effect of Sequestration

The sequestration will reduce the amount available for activities under health professions educational initiatives program to $7,656,000. This will support approximately 30 projects. This is a reduction of approximately 4 projects or 11.8% from the FY 1986 Appropriation level.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Program Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Area Health Education Centers...............	$18,000,000	-$774,000	$17,226,000
AHEC Projects..........	(16,200,000)	(-697,000)	(15,503,000)
AHEC Special Initiatives...........	(1,800,000)	(-77,000)	(1,723,000)

Effect of Sequestration

The sequestration will reduce the amount available for the area health education centers program to $17,226,000. This will support approximately 17 AHEC projects and 18 special initiative projects. This is a reduction of 3 AHEC projects or 15% from the FY 1986 Appropriation level.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Program Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Disadvantaged Assistance...........	$25,500,000	-$1,097,000	$24,403,000
Health Career Opportunity Projects.............	(20,400,000)	(-877,000)	(19,523,000)
Student Assistance Stipends.............	(5,100,000)	(-220,000)	(4,880,000)

Effect of Sequestration

The sequestration will reduce the amount available for the Disadvantaged Assistance to $24,403,000. This is $1,097,000 less than the FY 1986 Appropriation.

The sequestration will reduce the amount available for health career opportunity projects to $19,523,000. This will support approximately 151 projects. This is a reduction of 4 projects or 2.6% from the FY 1986 Appropriation level.

The sequestration will reduce the amount available for the stipends for the health career opportunity program students of exceptional financial need program to $4,880,000. This will provide support for approximately 488 recipients. This is a reduction of 22 recipients or 4.3% from the FY 1986 Appropriation level.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Program Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
H.P. Analytical Studies and Reports..........	$2,000,000	-$86,000	$1,914,000

Effect of Sequestration

The sequestration will reduce the amount available for health professions data analysis activities to $1,914,000. This will support approximately 19 projects. This is a reduction of 1 project from the FY 1986 Appropriation level.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Program Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Nurse Education			
Advanced Nurse Education..........	$16,500,000	-$ 710,000	$15,790,000
Nurse Practitioner/ NU Midwife.........	12,000,000	-516,000	11,484,000
Nurse Special Projects...........	9,500,000	-408,000	9,092,000
Professional Nurse Traineeships.......	11,500,000	-495,000	11,005,000
Nurse Research Fellowships........	2,000,000	-86,000	1,914,000
Nurse Research Grants.............	9,700,000	-417,000	9,283,000
Nurse Anesthetists..	800,000	-34,000	766,000
Nurse Demonstration Projects...........	1,350,000	-58,000	1,292,000
Nurse Faculty Fellowships........	550,000	-24,000	526,000
Total............	$63,900,000	-$2,748,000	$61,152,000

Effect of Sequestration

The sequestration will reduce the amount available for the advanced nurse education program to $15,790,000. This will provide support for approximately 91 projects enrolling approximately 2,000 nursing students at the master's or higher level. This is a reduction of about 5 projects or 5.2% and 200 nursing students or 9.1% enrolled in those programs from the FY 1986 Appropriation level.

The sequestration will reduce the amount available for the nurse practitioner/nurse midwife program to $11,484,000. This will provide support for approximately 60 projects. This is a reduction of 7 projects or 10.4% from the FY 1986 Appropriation level.

The sequestration will reduce the amount available for the nurse special project program to $9,092,000. This will provide support for approximately 72 projects. This is a reduction of approximately 3 projects or 4% from the FY 1986 Appropriation level.

The sequestration will reduce the amount available for the professional nurse traineeship program to $11,005,000. This will provide support for approximately 157 institutions providing advanced training to approximately 4,100 students. This is a reduction of 100 students or 2.4% from the FY 1986 Appropriation level.

The sequestration will reduce the amount available for the nurse research fellowships program to $1,914,000. This will provide support for approximately 155 grants to individuals and institutions in support of predoctoral and postdoctoral nursing fellowships. This is a reduction of 11 projects or 6.6% from the FY 1986 Appropriation level.

The sequestration will reduce the amount available for the nursing research grants program to $9,283,000. This will support approximately 80 nursing research grants. This is a reduction of 4 projects or 5% supported by the FY 1986 Appropriation level.

The sequestration will reduce the amount available for the nurse anesthetist program to $766,000. This will support grants to approximately 75 institutions and 574 trainees. This is the same number of institutions that would be supported by the FY 1986 Appropriation level funded at a 4.3% reduction.

The sequestration will reduce the amount available for the nurse demonstration project program to $1,292,000. This will provide support for approximately 6 projects. This is the same number of projects as supported by the FY 1986 Appropriation level funded at a 4.3% reduction.

The sequestration will reduce the amount available for the nurse faculty fellowships program to $526,000. This will provide support for approximately 526 awards to faculty. This is a reduction of 24 awards or 4.4% to faculty from the FY 1986 Appropriation level.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Program Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Bureau of Health Professions Direct Operations...	$20,200,000	-$869,000	$19,331,000

Effect of Sequestration

The sequestration will reduce the amount available for health professions direct operations to $19,331,000. These funds will pay operating expenses associated with the administration and operation of approximately 30 national health professions programs and activities. Debt management and collection activities of student assistance programs will also be conducted at a slightly reduced level of operation from the FY 1986 Appropriation level.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Bureau of Health Maintenance Organizations and Resources Development

Effect of Sequestration

	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Local Planning	$15,680,000	-$674,000	$15,006,000

Effect of Sequestration

A proportionate reduction in the grant amounts provided on a per capita basis to 141 local Health Systems Agencies and nine States and Territories to maintain activities through September 30, 1986 under Title XV of the PHS Act.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Bureau of Health Maintenance Organizations and Resources Development

Effect of Sequestration

	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
State Health Planning and Development	$4,800,000	-$206,000	$4,594,000

Effect of Sequestration

A proportionate reduction in the grant amounts provided on a per capita basis to 57 States and Territories to maintain activities through September 30, 1986 under Title XV of the PHS Act.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Bureau of Health Maintenance Organizations and Resources Development

Effect of Sequestration

	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Planning Methods Development	$418,000	-$18,000	$400,000

Effect of Sequestration

A reduction in the amounts provided by contracts to Centers for Health Planning to maintain activities through September 30, 1986 under Title XV of the PHS Act.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Health Resources and Services Administration

Bureau of Health Maintenance Organizations and Resources Development

Effect of Sequestration

	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Outpatient Facility Construction	$5,000,000	-$215,000	$4,785,000

Effect of Sequestration

The sequestration will have no adverse affect on this activity.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Bureau of Health Maintenance Organizations and Resources Development

Effect of Sequestration

	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Health Teaching Facilities	$1,200,000	$52,000	$1,148,000

Effect of Sequestration

The sequestration will have no adverse impact on this activity.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Bureau of Health Maintenance Organizations and Resources Development

Effect of Sequestration

	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
BHMORD, Direct Operations	$20,700,000	-$890,000	$19,810,000

Effect of Sequestration

The sequestration will reduce contract, travel, training, and other discretionary activities.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Bureau of Health Care Delivery and Assistance

Effect of Sequestration

Buildings and facilities	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
	$750,000	-$32,000	$718,000

Effect of Sequestration

The sequestration would result in postponement of one or more of the nine maintenance and repair projects at the Gillis W. Long Hansen's Disease Center, Carville, Louisiana.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resoruces and Services Administration

Office of the Administrator

Effect of Sequestration

Program Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Office of the Administrator	$23,994,000	-$1,032,000	$22,962,000

Effect of Sequestration

The sequestration of $1,032,000 will reduce the amount available for the Office of the Administrator, Health Resources and Services Administration activity to $22,962,000. Operating expenses will be reduced by $26,000 for travel; $5,000 for transportation of things; $52,000 for rent, communications and utilities; $95,000 for printing and reproduction, $577,000 for other services (training, contracts, etc.); $15,000 for supplies and materials, $150,000 for equipment; and $112,000 for grants, subsidies and contributions.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Services

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Hospital and Health Clinics	$433,598,000	-$4,591,000	$429,007,000

Effect of Sequestration

Of the $433,598,000 provided in the FY 1986 appropriation for the Indian Health Service (IHS) Hospitals and Health Clinics activity, $4,591,000 (1.1%) will be sequestered.

The sequestration of $4,170,000 (1%) of funds provided in the FY 1986 appropriation for the provision of inpatient and outpatient services through the IHS Hospitals and Health Clinics activity will result in a reduction in program activities. Every effort will be made to minimize the reduction of services by reducing travel and training and the purchase of supplies and equipment; however, there may be a minimal reduction in the provision of services.

Of the $3,976,000 provided in the FY 1986 appropriation for the support of Emergency Medical Services, $40,000 (1%) will be sequestered. The sequestration will eliminate support for approximately 3 emergency medical technicians (EMTs). After sequestration, $3,936,000 would remain available in FY 1986 to support 260 EMTs staffing 65 tribal ambulance service programs which provide emergency medical care on a 24-hour basis.

Of the $2,982,000 provided in the FY 1986 appropriation for the support of indirect costs for tribal contracts, $30,000 (1%) will be sequestered. After sequestration, $2,952,000 would remain available for indirect costs to assist tribal contractors to operate and manage their own health programs under the authority of P.L. 93-638, The Indian Self-Determination and Education Assistance Act.

Of the $1,889,000 provided in the FY 1986 appropriation for the support of the Model Diabetes program, $19,000 (1%) will be sequestered. The sequestering may result in a minimal reduction in services but every effort will be made to minimize a reduction in services by reducing training and the purchase of supplies and equipment. After sequestration, $1,870,000 will remain available for support of the Model Diabetes program in FY 1986.

The sequestration of $332,000 (4.3%) of funds provided in the FY 1986 appropriation for the administrative overhead costs at the IHS hospitals and health clinics will result in a reduction of administrative support.

The following table provides a summary of the sequestration by activity/project as well as impact data:

Activity/Project	FY 1986 Appropriation	Sequestration		FY 1986 Available After Sequestering
		Amount	%	
Provision of Inpatient and Outpatient Services	$417,033,000	-$4,170,000	-1%	$412,863,000
Emergency Medical Services (EMTs Supported)	3,976,000 (263)	-40,000 (-3)	-1% (-1.1%)	3,936,000 (260)
Indirect Costs for P.L. 93-638 Contracts	2,982,000	-30,000	-1%	2,952,000
Model Diabetes Program	1,889,000	-19,000	-1%	1,870,000
Administrative Overhead Costs	7,718,000	-332,000	-4.3%	7,386,000
Total	$433,598,000	-$4,591,000	-1.1%	$429,007,000
Impact Data:				
Average Daily Patient Census (excluding newborns)	990	*		990
Hospital Admissions (excluding newborns)	76,200	*		76,200
Average Length of Stay (days)	4.8	*		4.8
Births	13,200	*		13,200
Outpatient Visits (all clinics)	3,342,000	*		3,342,000

*Minimal, if any, impact.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Services

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Dental Services	\$25,879,000	-\$259,000	\$25,620,000

Effect of Sequestration

Of the \$25,879,000 provided in the FY 1986 appropriation for the Dental Services activity, \$259,000 (1%) will be sequestered. The sequestering may result in a minimal reduction in services, but every effort will be made to minimize the reduction of services by reducing travel and training and the purchase of supplies and equipment.

Impact Data	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Persons Treated	258,000	*	258,000
Services Provided	1,904,000	*	1,904,000

*Minimal, if any, impact.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Services

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Mental Health	$11,449,000	-$115,000	$11,334,000

Effect of Sequestration

Of the $11,449,000 provided in the FY 1986 appropriation for the Mental Health activity, $115,000 (1%) will be sequestered. The sequestering may result in a minimal reduction of services, but every effort will be made to minimize the reduction of services by reducing travel and training and the purchase of supplies and equipment.

Impact Data	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Client Contacts	180,000	*	180,000

*Minimal, if any, impact.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Services

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Alcoholism	$24,627,000	-$246,000	$24,381,000

Effect of Sequestration

Of the $24,627,000 provided in the FY 1986 appropriation for the Alcoholism activity, $246,000 (1%) will be sequestered. The sequestering may result in a minimal reduction in services, but every effort will be made to minimize the reduction of services by reducing travel and training and the purchase of supplies and equipment.

Activity/Project	FY 1986 Appropriation	Sequestration		FY 1986 Available After Sequestering
		Amount	% 1/	
Warm Springs Demonstration	$124,000	-$1,000	- .8%	$123,000
University of Washington Fetal Alcoholism Research	99,000	-1,000	-1.0%	98,000
All Other Alcoholism Projects	24,404,000	-244,000	-1.0%	24,160,000
Total	24,627,000	-246,000	-1.0%	24,381,000
Impact Data:				
Outpatient Visits	339,000	*		339,000
Inpatient Days	206,000	*		206,000

*Minimal, if any, impact.

1/ The actual reduction is 1%, but because of rounding the percentage reduction shown by project varies from 1%.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Services

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Maintenance and Repair	$8,621,000	-$86,000	$8,535,000

Effect of Sequestration

Of the $8,621,000 provided in the FY 1986 appropriation for maintenance and repair of the IHS hospitals and health centers, $86,000 (1%) will be sequestered.

The $86,000 sequestering will have minimal impact on this activity. For example, the sequestering may not permit some routine maintenance and repair such as painting, minor wall repairs, and/or minor electrical work to be done at several facilities.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Services

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Contract Health Care	$170,040,000	-$1,700,000	$168,340,000

Effect of Sequestration

Of the $170,040,000 provided in the FY 1986 appropriation for the Contract Health Care activity, $1,700,000 (1%) will be sequestered.

The sequestration of $1,700,000 would lead to the following reduction of services available under contract health care.

Impact Data	FY 1986 Appropriation	Sequestration		FY 1986 Available After Sequestering
		Amount	%	
Hospital - Admissions	21,745	-233	-1.1%	21,512
Days	102,200	-1,095	-1.1%	101,105
Average Daily Patient Load	280	-3	-1.1%	277
Ambulatory Outpatient Visit	242,178	-2,421	-1.0%	239,757
Dental Patients	40,568	-406	-1.0%	40,162

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Services

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Sanitation	$20,804,000	-$208,000	$20,596,000

Effect of Sequestration

Of the $20,804,000 provided in the FY 1986 appropriation for the Sanitation activity, $208,000 (1%) will be sequestered. The sequestering may result in a minimal reduction in services, but every effort will be made to minimize the reduction of services by reducing travel and training and the purchase of supplies and equipment.

Impact Data	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Environmental Health Services	259,000 1/	*	259,000

*Minimal, if any, impact.

1/ This estimate is significantly lower than previous estimates because of the introduction of a revised reporting system during FY 1985.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Services

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Public Health Nursing	$12,441,000	-$124,000	$12,317,000

Effect of Sequestration

Of the $12,441,000 provided in the FY 1986 appropriation for the Public Health Nursing activity, $124,000 (1%) will be sequestered. The sequestration may result in a minimal reduction in services, but every effort will be made to minimize the reduction of services by reducing travel and training and the purchase of supplies and equipment.

Impact Data	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Public Health Nursing Services	610,000	*	610,000
No. of Families Served	55,000	*	55,000

*Minimal, if any, impact.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Services

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Health Education	$3,614,000	-$36,000	$3,578,000

Effect of Sequestration

Of the $3,614,000 provided in the FY 1986 appropriation for the Health Education activity, $36,000 (1%) will be sequestered. The sequestration may result in a minimal reduction in services, but every effort will be made to minimize the reduction of services by reducing travel and training and the purchase of supplies and equipment.

Impact Data	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Health Education Services	223,000	*	223,000

*Minimal, if any, impact.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Services

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Community Health Representatives	$25,844,000	-$259,000	$25,585,000

Effect of Sequestration

Of the $25,844,000 provided in the FY 1986 appropriation for the Community Health Representatives activity, $259,000 (1%) will be sequestered. The sequestering may result in a minimal reduction in services, however, tribal contractors will likely make every effort to minimize the reduction of services by reducing travel and training and the purchase of supplies and equipment.

Impact Data	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
No. of CHRs Supported	1,500	*	1,500
Encounters (Individuals and Groups of Individuals)	8,127,000	*	8,127,000

*Minimal, if any, impact.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Services

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Hepatitis B Screening and Immunization Program (Alaska)	$2,705,000	-$27,000	$2,678,000

Effect of Sequestration

Of the $2,705,000 provided in the FY 1986 appropriation for the Alaska Hepatitis B Screening and Immunization Program, $27,000 (1%) will be sequestered. The sequestering may result in a minimal reduction in services, but every effort will be made to minimize the reduction of services by reducing travel and training and the purchase of supplies and equipment.

Impact Data	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Services Provided:			
No. of Patients Vaccinated	12,000	*	12,000
No. of Patients Screened	20,000	*	20,000

*Minimal, if any, impact.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Services

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Urban Health Projects	$9,741,000	-$97,000	$9,644,000

Effect of Sequestration

Of the $9,741,000 provided in the FY 1986 appropriation for the Urban Health Program, $97,000 (1%) will be sequestered. The sequestering may result in a minimal reduction of services, however, contractors will likely make every effort to minimize the reduction of services by reducing travel and training and the purchase of supplies and equipment.

Impact Data:	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
No. Contract Projects	37	*	37
No. of Persons Served	400,000	*	400,000

*Minimal, if any, impact.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Services

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Indian Health Manpower	$6,460,000	-$65,000	$6,395,000

Effect of Sequestration

Of the $6,460,000 provided in the FY 1986 appropriation for the Indian Health Manpower program, $65,000 (1%) will be sequestered.

The sequestration will reduce the number of scholarships granted and extern placements funded by 5 less scholarships and 3 less extern placements.

Impact Data:	FY 1986 Appropriation	Sequestration Amount	Sequestration % 1/	FY 1986 Available After Sequestering
Section 102 Health Professions Recruitment Program	$504,000	-$5,000	-1.0%	$499,000
(In-Med Program)	(279,000)	(-3,000)	(-1.1%)	(276,000)
(MPH Programs)	(225,000)	(-2,000)	(-0.9%)	(223,000)
No. of Projects	5	-0-		5
Section 103 Health Professions Preparatory Program	$1,695,000	-$17,000	-1.0%	$1,678,000
No. of Scholarships	150	-2	-1.3%	148
Section 338G (PHS Act) Health Professions Scholarships	$3,360,000	-$34,000	-1.0%	$3,326,000
No. of Scholarships	298	-3	-1.0%	295
Section 105 Extern Program	$901,000	-$9,000	-1.0%	$892,000
No. of Externs	298	-3	-1.0%	295
Total Budget Authority	$6,460,000	-$65,000	-1.0%	$6,395,000

1/ The actual reduction is 1%, but because of rounding the percentage reduction shown by activity varies from 1%.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Services

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Tribal Management	$1,988,000	-$20,000	$1,968,000

Effect of Sequestration

Of the $1,988,000 provided in the FY 1986 appropriation for the Tribal Management Activity, $20,000 (1%) will be sequestered.

The sequestration will eliminate support for one project in the area of tribal training, evaluation or development or improvement of tribal management systems.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Services

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Direct Operations	$60,383,000	-$2,596,000	$57,787,000

Effect of Sequestration

Of the $60,383,000 provided in the FY 1986 appropriation for the Indian Health Services Direct Operations activity, $2,596,000 (4.3%) will be sequestered.

The sequestration will result in a reduction of travel, supplies, training, and equipment for IHS management staff.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Services

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Reimbursements (Medicaid)	$25,748,000	-$256,000	$25,492,000

Effect of Sequestration

The Gramm-Rudman-Hollings Deficit Reduction Act also requires the sequestering of reimbursements received from non-federal sources. For the IHS, these collections represent medicaid reimbursements from the States for IHS beneficiaries served in IHS facilities and reimbursements from non-federal sources, such as the state of Alaska, for non-IHS beneficiaries served in IHS facilities. The sequestering will result in $256,000 of the estimated FY 1986 collections ($24,100,000 for Medicaid and $1,648,000 from other non-federal sources) being witheld from obligation in FY 1986.

The $256,000 (1%) sequestration may have a minimal impact on the activities supported with these funds, such as reduced consultant services, supplies, etc.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Services

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Permanent Budget Authority (Operation and Maintenance of Quarters)	$3,000,000	-$30,000	$2,970,000

Effect of Sequestration

The IHS estimates that $3 million will be collected from IHS employees housed in IHS personnel quarters in FY 1986. Under the authority of Section 320 of P.L. 98-473, in FY 1985 a new account was established to deposit these collections. The collections are available, until expended, for the maintenance and operation of IHS personnel quarters.

The sequestering will result in $30,000 of the estimated FY 1986 collections being witheld from obligation in FY 1986.

The $30,000 (1%) sequestration may have a minimal impact on the activities surported with these funds. For example, the sequestering may not permit some routine maintenance and repairs, such as painting.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Facilities

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Hospitals			
New and Replacement	$12,386,000	-$124,000	$12,262,000
Modernization and Repair	$ 3,081,000	-$ 31,000	$ 3,050,000

Effect of Sequestration

The proposed sequestration of $124,000 (1%) in FY 1986 should have minimal, if any, impact on phase I construction of the Rosebud project.

The reduction of $31,000 (1%) in FY 1986 for modernization and repair should have minimal, if any, impact on the modernization and repair projects.

The following is a listing of the effect of sequestration on the projects funded in FY 1986:

Project	FY 1986 Appropriation	Sequestration		FY 1986 Available After Sequestering
		Amount	% 1/	
Hospitals:				
New and Replacement:				
Rosebud, SD Replacement Hospital-Phase I constr. and long-lead equipment	$10,408,000	-$104,000	-0.99%	$10,304,000
Kotzebue, AK Replacement Hospital-Planning and design	1,978,000	-20,000	-1.01%	1,958,000
Total	12,386,000	-124,000	-1.0%	12,262,000
Modernization and Repair:				
Ft. Defiance, AZ Hospital	1,292,000	-14,000	-1.08%	1,278,000
Belcourt, ND Hospital	696,000	-7,000	-1.0%	689,000
Bethel, AK Hospital-Personnel Quarters	497,000	-5,000	-1.0%	492,000
Colville, WA Health Center	176,000	-1,000	-0.57%	175,000
Albuquerque Area Hospitals: (Zuni, Acoma-Canoncito-Laguna, Albuquerque, and Santa Fe, NM)	420,000	-4,000	-0.95%	416,000
Total	3,081,000	-31,000	-1.0%	3,050,000

1/ The actual reduction is 1%, but because of rounding the percentage reduction shown by project varies from 1%.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Facilities

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Outpatient Care Facilities	$722,000	-$7,000	$715,000

Effect of Sequestration

The proposed sequestration of $7,000 (1%) in FY 1986 should have minimal, if any, impact on the planning and design of the following facilities:

Project	FY 1986 Appropriation	Sequestration		FY 1986 Available After Sequestering
		Amount	% 1/	
Wagner, SD	$100,000	-$1,000	-1.0%	$ 99,000
Toppenish, WA	622,000	- 6,000	-0.96%	616,000
Total	722,000	- 7,000	-0.97%	715,000

1/ The actual reduction is 1%, but because of rounding the percentage reduction shown by project varies from 1%.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Facilities

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Sanitation Facilities	$24,850,000 1/	-$249,000	$24,601,000

Effect of Sequestration

The sequestered amount of $249,000 (1%) will preclude the provision of sanitation facilities to approximately 30 new Indian homes, or approximately 1% of the estimated 2,880 homes for which funds were appropriated in FY 1986.

Inpact Data	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
No. of New and Improved Homes	2,880 1/	-30 (-1.0%)	2,850

1/ Includes $4,970,000 for the construction of sanitation facilities to approximately 300 new homes in support of the Navajo and Hopi Indian Relocation Act.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Indian Health Facilities

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Personnel Quarters	$5,626,000	-$56,000	$5,570,000

Effect of Sequestration

The proposed sequestration of $56,000 (1%) in FY 1986 should have minimal, if any, impact on the construction and equipping of the required units of staff quarters for the following facilities:

Project	FY 1986 Appropriation	Sequestration Amount	Sequestration % 1/	FY 1986 Available After Sequestering
Sacaton, AZ-Renovate 8 units of personnel quarters	$ 159,000	-$ 1,000	-0.63%	$ 158,000
Ft. Thompson, SD-Constr. 13 units of personnel quarters	1,292,000	-13,000	-1.0%	1,279,000
Kanakanak, AK-Constr. 26 units of personnel quarters	4,175,000	-42,000	-1.0%	4,133,000
Total	5,626,000	-56,000	-1.0%	5,570,000

1/ The actual reduction is 1%, but because of rounding the percentage reduction shown by project varies from 1%.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR DISEASE CONTROL

Disease Control

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Preventive Health Services:			
Preventive health & health services block grants:			
Grants	$90,958,000	$3,911,000	$87,047,000
Program support	525,000	23,000	502,000
Subtotal	91,483,000	3,934,000	87,549,000
Prevention centers	1,500,000	64,000	1,436,000
Sexually transmitted diseases:			
Grants	46,511,000	2,000,000	44,511,000
Program operations	9,774,000	420,000	9,354,000
Subtotal	56,285,000	2,420,000	53,865,000
Immunization:			
Grants	47,359,000	2,036,000	45,323,000
Program operations	8,235,000	354,000	7,881,000
Vaccine stockpile	4,000,000	172,000	3,828,000
Subtotal	59,594,000	2,562,000	57,032,000
Infectious diseases:			
T.B. grants	5,000,000	215,000	4,785,000
AIDS:			
New drugs	6,900,000	297,000	6,603,000
Hot line	2,000,000	86,000	1,914,000
Alternate test sites ..	10,380,000	446,000	9,934,000
Other AIDS	45,645,000	1,963,000	43,682,000
Subtotal	64,925,000	2,792,000	62,133,000
Other infectious diseases	36,773,000	1,581,000	35,195,000
Subtotal	106,698,000	4,588,000	102,110,000
Chronic & environmental disease prevention:			
Diabetes grants	5,000,000	215,000	4,785,000
Designer drugs	1,000,000	43,000	957,000
Other chronic & environ. disease prevention	24,425,000	1,050,000	23,375,000
Subtotal	30,425,000	1,308,000	29,117,000

Program/ Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Occupational safety and health:			
Research	58,923,000	2,534,000	56,389,000
Training	8,760,000	377,000	8,383,000
Subtotal	67,683,000	2,911,000	64,772,000
Epidemic services:			
Epidemic svcs. activities	51,766,000	2,226,000	49,540,000
User fees	-466,000	-19,000	-447,000
Subtotal	51,300,000	2,207,000	49,093,000
Buildings & facilities:			
Repairs & improvements	1,810,000	78,000	1,732,000
Equipment, virology lab.	1,987,000	85,000	1,902,000
Subtotal	3,797,000	163,000	3,634,000
Program management	3,096,000	133,000	2,963,000
TOTAL	471,861,000	20,290,000	451,571,000
Other Reductions:			
Offsetting collections (non-Federal 401(c) authority)	1,100,000	47,000	1,053,000

Effect of Sequestration

Preventive Health & Health Services Block Grant

The sequestering of $3,911,000 from block grant funds reduces the Federal share in the cost of public health programs for which State and local health departments have the primary responsibility. These grants constitute a relatively small proportion of the total State and local expenditures for public health (e.g., the percentage for FY 1983 was 1.5 percent). The decreased funding will, to varying degrees, affect such State programs as: fluoridation; rodent control; hypertension; emergency medical services; home health; rape services; risk reduction; and comprehensive public health services such as tuberculosis.

The reduction in program operations will result in fewer dollars for travel to audit State grants.

Prevention Centers

The prevention centers reduction of $64,000 will reduce the funds available for each center.

Sexually Transmitted Diseases

The proposed cutbacks of $420,000 in direct operations and $2,000,000 in grants will affect further implementation of a national chlamydia control program. Special demonstration projects aimed at developing cost-effective methodologies for the control of chlamydia will be reduced and funding for chlamydia testing, surveillance, and intervention will be discontinued.

Strategically located Regional laboratories which are planned for opening in FY 1986 and are intended to monitor and track antimicrobial resistant disease, will be deferred. In addition, planned research projects for FY 1986 will not be implemented. These include three projects whose results have potential impact upon disease control strategy nationwide and which relate to five of the six priority 1990 objectives: (1) Pelvic Inflammatory Disease (PID) - the purchase of a database from Sweden which compares results of clinical diagnoses and laparoscopy tests will be invaluable in helping to set direction for ongoing PID research; (2) Adolescent Sexually Transmitted Diseases - this project will compare STD knowledge among inner-city teenagers before and after education which emphasizes prevention methods that are particularly suitable for adolescents; and (3) Human Papillomavirus - this project will explore the epidemiology of HPV and its relation to cervical cancer.

Immunization

In FY 1985, immunization grants totaled $42.4 million, of which $26.1 million was used for the purchase of vaccine and $16.3 million was used to support State and local immunization program operations. In FY 1986, due to vaccine price increases, $36.9 million will be used to provide the same proportion of vaccine as in FY 1985; consequently, Federal support for State and local immunization program operations, including the vaccine delivery system and surveillance activities, will decrease to $8.4 million.

In addition, the Gramm-Rudman reductions in program operations will postpone the annual U.S. Immunization Survey. This survey provides information on national immunization levels which is essential for future planning and decision making.

Funds available for the purchase of vaccine for the stockpile will be reduced by $172,000, increasing the length of time to complete the stockpile.

Infectious Diseases

The sequestering of $215,000 in TB grant funds will reduce the average size of the awards by $4,434 and reduce the TB prevention level of effort by 4.3%, unless State or local funds can be used to replace the decrease.

Funds available to purchase chemotherapeutic agents for the treatment of patients with AIDS will be reduced by $297,000. The effect will be a reduction in the number of patients treated.

The reduction of $86,000 for the 24-hour AIDS hotline will decrease the level of services available to the callers by reducing the number of telephone call receivers from 39 to 35.

Alternate test site awards to States will be decreased by $446,000, or an average of $8,900 per State and will require additional State or local funding.

Since neither proven antiviral drugs nor a vaccine are available, health education/risk reduction activities (including testing and counseling among groups at risk for AIDS) are the main interventions for helping reduce the spread of HTLV-III/LAV. The $1,963,000 reduction in other AIDS activities will reduce the average size of the award to States and local health agencies by 4.3% for health education/risk reduction activities in capacity building, augmentation of existing health education/risk reduction programs, and demonstration projects. Funds available to fund innovative health education/risk reduction projects will be reduced by 4.3%. The sequestering will also decrease the size and/or number of surveillance projects and epidemiology studies. This reduction also includes a reduction of $47,000 resulting from the sequestering of 4.3% of anticipated collections from non-federal sources for services provided.

The sequestering of $1,581,000 of other infectious diseases funds will delay the purchase of state-of-the-art scientific equipment necessary to keep CDC's research and laboratory activities on the leading edge of scientific change.

Chronic and Environmental Disease Prevention

The sequestering of $215,000 of diabetes project funds will reduce the number of major complication-specific interventions funded and reduce the size of the awards to project States from $195,490 to $187,084.

A reduction of $43,000 in the new designer drugs program will reduce the number of extramural projects by one.

The sequestration of $1,050,000 in other chronic and environmental diseases prevention programs will reduce modestly (4.3%) the level of research and services provided in this activity including environmental health, community health promotion, nutrition, technology transfer, dental disease prevention, diabetes, laboratory services, and chronic diseases.

Occupational Safety and Health

The sequestering of $2,534,000 will affect both intramural and extramural research into the ten leading work-related diseases and injuries: occupational lung diseases; musculoskeletal injuries, occupational cancers; severe occupational traumatic injuries, occupationally related cardiovascular diseases; disorders of reproduction; neurotoxic disorders; noise-induced loss of hearing; dermatologic conditions; and psychologic disorders.

Sequestering of $377,000 in occupational safety and health training activities will reduce the size of the award for the 15 Educational Resource Centers by an average of $169,000. Increased university and private sector financing could replace Federal funding.

Epidemic Services

The sequestration of $2,207,000 will delay the purchase of state-of-the-art scientific equipment as it is developed and placed on the market for CDC's laboratory and surveillance activities to make them more timely and efficient.

Building & Facilities

The sequestration of $78,000 in repair and improvement activities will delay making minor repairs to the CDC facilities.

The reduction of $85,000 for equipping the not yet completed virology laboratory will result in a delay of purchasing the equipment for its efficient operation.

Program Management

The effect of sequestering $133,000 will be diminished by the improved management of travel, printing, purchases of equipment, and by the improved use of office automation.

Reimbursement from Non-Federal Sources

The effect of sequestering $47,000 of the anticipated collections from non-federal sources will require that infectious disease activities be reduced to offset the actual cost collections from non-federal users of CDC services.

In summary, except for epidemic aid surveillance, and grants to States for the purchase of vaccine, all programs within CDC will be affected, to some minor extent, by the sequestering action.

NATIONAL INSTITUTES OF HEALTH

	FY 1986 ENACTED	FY 1986 G/R/H W/COM	FY 1986 REVISED
NATIONAL INSTITUTES OF HEALTH '			
Research project grants:			
Amount	3,041,430	-130,784	2,910,646
Number non-competing grants (non-add)	(12,676)	---	(12,676)
Number competing (non-add)	(6,100)	---	(6,100)
Total number (non-add)	(18,776)	---	(18,776)
Subtotal, research project grants	3,041,430	-130,784	2,910,646
Other research:			
Research centers	487,829	-20,975	466,854
Other research	311,242	-13,383	297,859
Research & development contracts	373,100	-16,045	357,055
Research management and support	215,059	-9,247	205,812
Subtotal, other research	1,387,230	-59,650	1,327,580
Intramural research:			
Intramural research obligations	584,308	-25,125	559,183
Subtotal, intramural research	584,308	-25,125	559,183
Research training	218,808	-9,409	209,399
Number of trainees (non-add)	(10,372)	(-674)	(9,698)
Disease control/construction	72,478	-3,117	69,361
National Library of Medicine	57,808	-2,486	55,322
Office of the Director	116,992	-5,031	111,961
Buildings and facilities	14,900	-641	14,259
AIDS (non-add)	(140,723)	(-6,051)	(134,672)
Total, National Institutes of Health	5,493,954	-236,243	5,257,711

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

National Cancer Institute

Effect of Sequestration

Mechanism	1986 Appropriation	Sequestration (-)	Available After Sequestering
Research project grants...	$585,429,000	$25,173,000	$560,256,000
Research centers..........	85,979,000	3,697,000	82,282,000
Other research............	69,651,000	2,995,000	66,656,000
Research training.........	30,838,000	1,326,000	29,512,000
R&D contracts.............	149,587,000	6,432,000	143,155,000
Intramural research.......	205,473,000	8,836,000	196,637,000
Research management and support................	59,902,000	2,576,000	57,326,000
Cancer prevention and control................	63,878,000	2,747,000	61,131,000
Construction..............	2,000,000	86,000	1,914,000
Total.................	$1,252,737,000	$53,868,000	$1,198,869,000

Effect of Sequestration

The sequestration will permit the funding of 2,151 noncompeting research project grants at a level of $389,366,000 compared to $406,861,000 within the appropriation. This represents a 5.4 percent increase in average cost over 1985 and a 5.2 percent reduction from historical commitment levels. A total of 908 new and competing renewal research project grants at $164,598,000 will be funded under sequestration, compared to $171,993,000 within the appropriation. This represents an 8.4 percent increase in average cost over 1985 and a 7.4 percent reduction from historical recommended levels. Any grants awarded prior to sequestration will not be amended during FY 1986 in order that research already begun will not be disrupted.

The sequestration will permit the funding of 57 cancer centers at a level of $82,282,000 compared to 58 centers at $85,979,000 within the appropriation. Thus negotiations of approximately five percent will be necessary for noncompeting centers while competing centers will be funded at approximately 80 percent of peer-review recommended levels. This compares with competing reductions of an average of 10 percent in 1985. This will require some delay in initiating shared equipment purchases and in staffing some resources for research projects conducted at the centers.

In the mechanisms of "Other research" the sequestration will permit support of 117 promising researchers in the Careers programs compared to 122 under the appropriation. The clinical cooperative research program will support 228 cooperative agreements with regional research hospitals with a funding level of $48,045,000 compared to 255 awards and $50,204,000 under the appropriation. Reductions will be taken below current funding levels for both noncompeting and competing awards. This will reduce the number of patients enrolled in clinical trials under this mechanism. The minority biomedical research program, clinical education program and the organ systems program will each receive 95.6 percent of the support provided in the appropriation. This will require reductions of noncompeting grants in the organ system and clinical education programs and a reduction of funds available to support new research in the program.

In the National Research Service Act (NRSA) program, the sequestration will permit the funding of 1,231 trainees with $29,512,000 compared to 1,286 trainees and $30,838,000 under the appropriation.

Research supported with the R&D contract mechanism will fund 457 contracts at $143,155,000 after the sequestration compared to 471 awards and $149,587,000 under the appropriation.

The sequestration will permit an Intramural research program level of $196,637,000 compared to $205,473,000 in the appropriation level. A reduction in staffing will be achieved through use of a hiring plan to permit accessions at a lower rate than separations in order to permit a reduction to the new staffing level with as little a disruption of research efforts as possible. At the sequestration level, equipment purchases will be delayed and administrative reductions in travel and the purchase of supplies will be initiated.

The sequestration will permit the funding of oversight and administrative support for the research programs of the Institute at a level of $57,326,000 compared to $59,902,000 within the appropriation. This will reduce some public information efforts during FY 1986 from those planned under the appropriation.

Within the Cancer prevention and control programs the sequestration will permit funding of $61,131,000 in research compared to $63,878,000 under the appropriation. This will require the delay of some prevention initiatives and some research into changes in diet and lifestyle.

The sequestration will permit the restoration and upgrading of cancer research facilities with $1,914,000 compared to $2,000,000 under the appropriation.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICES

National Heart, Lung, and Blood Institute

Effect of Sequestration

Program/Activity	1986 Appropriation	Sequestration	Available After Sequestering
Research project grants..............	$533,095,000	-$22,923,000	$510,172,000
Research centers......	87,046,000	-3,743,000	83,303,000
Other research........	36,263,000	-1,559,000	34,704,000
Research training.....	40,206,000	-1,729,000	38,477,000
R & D contracts.......	62,345,000	-2,681,000	59,664,000
Intramural research...	60,790,000	-2,614,000	58,176,000
Research management and support..............	36,194,000	-1,556,000	34,638,000
Construction..........	3,300,000	-142,000	3,158,000
Total	859,239,000	-36,947,000	822,292,000

Effect of Sequestration

The sequestration will permit the funding of 1,822 noncompeting research project grants at a level of $354,276,000, compared to $370,194,000 in the appropriation. This represents a 5.6 percent increase in average cost over 1985 and a 4.3 percent reduction from historical commitment levels. A total of 885 new and competing research project grants at $154,784,000 will be funded under sequestration, compared to $161,739,000 at the appropriations level. This represents a .1 percent decrease in average cost from 1985 and a 7.1 percent reduction from historical recommended levels. Any grant awarded prior to sequestration will not be amended during FY 1986 in order that research already begun will not be disrupted.

The Institute will fund 60 centers at a level of $83,303,000 compared to the appropriation level of $87,046,000, a reduction of 4.3%. Because a majority of the centers have December 1 start dates and awards had already been processed, the remaining centers will be negotiated downward by 10% from recommended levels.

The Institute will fund research career grants, cooperative clinical research, grants Minority Biomedical Research Support grants, conference grants, and demonstration and education grants, at a level of $34,704,000 compared to $36,263,000 at the appropriation level. The same number of grants will be funded, but they will be negotiated downward by 4.3%.

The Institute will fund research training at $38,477,000 compared to $40,206,000 in the appropriation. This level will reduce the number of full time training positions from 1,710 to 1,627.

The Institute will fund research contracts at a level of $59,664,000, compared to $62,345,000 in the appropriation. The Institute plans to discuss with the National Heart, Lung, and Blood Advisory Council whether to reduce the size and scope of all contract programs or eliminate certain programs.

The intramural research program of the Institute will operate at a level of $58,176,000 compared to $60,790,000 at the appropriation level. This reduction can be accomplished through hiring restrictions.

The research management and support activity will operate at a level of $34,638,000 compared to $36,194,000 at the appropriation level. The Institute will reduce travel, consultant services, and public education efforts. Part of the reduction will be achieved through hiring restrictions.

The construction program will operate at a level of $3,158,000 compared to $3,300,000 at the appropriation level. The number of awards will be reduced from 10 to 9.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

National Institute of Dental Research

Effect of Sequestration

Program/Activity	1986 Appropriation	Sequestration (-)	Available After Sequestering
Research project grants...............	$46,939,000	-$2,018,000	$44,921,000
Research centers.......	13,905,000	-598,000	13,307,000
Other research.........	5,632,000	-242,000	5,390,000
Research training......	4,562,000	-196,000	4,366,000
R&D contracts..........	4,686,000	-202,000	4,484,000
Intramural contracts...	20,688,000	-890,000	19,798,000
Research management and support..........	6,870,000	-295,000	6,575,000
Total............	103,282,000	-4,441,000	98,841,000

Effect of Sequestration

The sequestration will permit the funding of 248 noncompeting research project grants at a level of $27,682,000, compared to $28,926,000 within the appropriation. This represents a 4.8 percent decrease in average cost compared to 1985 and a 6.8 percent reduction from historical commitment levels. A total of 149 new and competing renewal research project grants at $17,239,000 will be funded under sequestration, compared to 149 such grants at $18,013,000 within the appropriation. This represents a 4.1 percent decrease in average cost compared to 1985 and a 8.6 percent reduction from historical recommended levels.

Any grant awarded prior to sequestration will not be amended during FY 1986 in order that research already begun will not be disrupted.

The total of $13,307,000 provided by the sequestration to support 16 research centers, a decrease of $598,000 below the appropriated level of $13,905,000 for research centers will maintain support for 16 research centers, but at a 4.3 percent reduction per center.

In the category of other research, the sequestration will allow funding of 127 awards at a level of $5,390,000, compared to 133 awards at a level of $5,632,000 within the appropriation, a decrease of 4.3 percent.

The sequestration will permit the funding of 204 trainees in the research training program at a level of $4,366,000, a decrease of $196,000 and 8 trainees as compared to 212 trainees at a funding level of $4,562,000 within the appropriation.

The sequestration provided $4,484,000 for research and development contracts, a decrease of $202,000, compared to $4,686,000 in this mechanism within the appropriation. Thirty-three research and development contracts will be supported.

The total of $19,798,000 provided by the sequestration for intramural research represents a decrease of $890,000 below the amount of $20,688,000 within the appropriation. This decrease will be absorbed through restriction of travel and the purchasing of equipment and supplies.

The total of $6,575,000 provided by the sequestration for research management and support represents a decrease of $295,000 below the amount of $6,870,000 within the appropriation. This decrease will be absorbed through restriction of travel and the purchasing of equipment and supplies.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

National Institute Arthritis, Diabetes, and Digestive and Kidney Diseases

Effect of Sequestration

Program/Activity	1986 Appropriation	Sequestration (-)	Available After Sequestering
Research project grants..............	$400,329,000	-$17,215,000	$383,114,000
Research centers.....	35,598,000	-1,531,000	34,067,000
Other research.......	19,263,000	-828,000	18,435,000
Research training....	26,730,000	-1,149,000	25,581,000
R&D contracts........	12,458,000	-536,000	11,922,000
Intramural research..	58,766,000	-2,527,000	56,239,000
Research management and support........	16,196,000	-696,000	15,500,000
Total............	569,340,000	-24,482,000	544,858,000

Effect of Sequestration

The sequestration will permit the funding of 1,790 noncompeting research project grants at a level of $262,475,000, compared to $274,669,000 within the appropriation. This represents a 2.4 percent increase in average cost over 1985 and a 13 percent reduction from historical commitment levels. A total of 836 new and competing renewal research project grants at $116,129,000 will be funded under sequestration, the same number to be funded for grants at $124,160,000 within the appropriation. This represents a 4.3 percent increase in average cost over 1985 and a 13 percent reduction from historical recommended levels.

Any grant awarded prior to sequestration will not be amended during FY 1986 in order that research already begun will not be disrupted.

In Research Centers, the sequestration will permit the funding of 45 awards at a level of $34,067,000, compared to $35,598,000 appropriated. This represents a 13 percent reduction form historical recommended levels. This compares with reductions of 4 percent in 1985.

Within Other Research, the sequestration of $828,000 from the appropriation level of $19,263,000 will result in a reduction of 17 research career program awards, a slight reduction in the Minority Biomedical Research Support program and a reduction in research meetings and symposia.

Training grants will be reduced from the $26,730,000 appropriated to $25,581,000 after the sequestering. This will result in a reduction of 49 full-time equivalent training positions.

Thirty-nine research and development contracts will be supported at the sequested level of $11,922,000 compared to 40 awards at the appropriation level of $12,458,000.

Intramural research will be reduced from $58,766,000 to $56,239,000 as a result of the sequestration order. The decrease of $2,527,000 will be accomplished primarily by eliminating replacement equipment purchases and by reductions in research supplies and materials. A staffing reduction will be accomplished through attrition as Visiting Scientists and Staff Fellows complete their appointments and are not replaced.

The sequestration in the Research Management and Support activities of $696,000 from the appropriated level of $16,196,000 will be shared by the three national advisory boards but will primarily impact on site-visits related to the review of research grants and contracts and on scientific meetings and symposia.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

National Institute of Neurological and Communicative Disorders and Stroke

Effect of Sequestration

Program/Activity	1986 Appropriation	Sequestration	Available After Sequestering
Research project grants.............	$294,273,000	-$ 12,654,000	$281,619,000
Research centers.....	30,150,000	-1,297,000	28,853,000
Other research.......	15,582,000	-670,000	14,912,000
Research training....	13,153,000	-566,000	12,587,000
R&D contracts........	13,102,000	-563,000	12,539,000
Intramural research..	49,952,000	-2,148,000	47,804,000
Research management and support........	17,150,000	-737,000	16,413,000
Total...........	433,362,000	-18,635,000	414,727,000

Effect of Sequestration

The sequestration will permit the funding of 1,273 noncompeting research project grants at a level of $180,025,000, compared to $188,114,000 within the appropriation. This represents a 9.2 percent increase in average cost over 1985 and a 4.3 percent reduction from historical commitment levels. A total of 646 new and competing renewal research project grants at $100,637,000 will be funded under sequestration, compared to 646 such grants at $105,159,000 within the appropriation. This represents a 6 percent increase in average cost over 1985 and a 4.3 percent reduction from historical recommended levels.

The sequestration will permit funding of 38 clinical research centers at a level of $28,853,000 compared with the appropriation of $30,150,000. This represents a downward negotiation of 4 percent compared with reductions of one percent in 1985.

Other research grants will be reduced $670,000 from the appropriation of $15,582,000 to a level of $14,912,000. This will result in a reduction of 10 clinical investigator development awards under the research career program, a reduction of two grant supported conferences on neurological and communicative disorders. Other research grants will be negotiated downward by 4.3 percent.

Any grant awarded prior to sequestration will not be amended during FY 1986 in order that research already begun will not be disrupted.

The sequestration will permit the support of a total of 598 National Research Service Award trainees for $12,587,000, a reduction of 27 trainees and $566,000 from the appropriation level of 625 trainees and $13,153,000.

The sequestration will permit funding of 64 research and development contracts at a level of $12,539,000, a reduction of 3 contracts and $563,000 from the appropriation of 67 contracts for $13,102,000. Contracts previously awarded will not be reduced.

The intramural research sequestration operating level of $47,804,000 is a reduction of $2,148,000 from the appropriation of $49,952,000. The program would achieve this reduction by postponing large equipment purchases and through limited hiring restrictions.

The research management and support sequestration operating level of $16,413,000 and is a reduction of $737,000 from the appropriation of $17,150,000. The reduction will be accomplished through limited hiring restrictions, deferring equipment purchases, and by exercising other management options.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

National Institute of Allergy and Infectious Diseases

Effect of Sequestration

Program/Activity	1986 Appropriation	Sequestration (-)	Available After Sequestering
Research project grants.....	$256,770,000	-$11,041,000	$245,729,000
Research centers............	6,106,000	-263,000	5,843,000
Other research..............	5,381,000	-231,000	5,150,000
Research training...........	11,382,000	-489,000	10,893,000
R&D contracts...............	26,493,000	-1,139,000	25,354,000
Intramural research.........	60,796,000	-2,614,000	58,182,000
Research management and support............. .	16,524,000	-711,000	15,813,000
Total..................	383,452,000	-16,488,000	366,964,000

Effect of Sequestration

Funds available after the sequestration will permit the award of 1,197 noncompeting research project grants at a level of $172,408,000, compared to $180,155,000 within the appropriation. This represents a 3 percent decrease in average cost from 1985 and a 10 percent reduction from historical commitment levels. A total of 526 new and competing renewal research project grants at $73,321,000 will be funded under sequestration, compared to 526 such grants at $76,615,000 within the appropriation. This represents a 6 percent increase in average cost over 1985 and an 8 percent reduction from historical recommended levels.

A total of 18 research centers will be funded after sequestration at a level of $5,843,000, compared to the same number at a level of $6,106,000 within the appropriation. Thus, downward negotiations of about 7 percent will be required on all center awards, compared to full funding in 1985.

Any grant awarded prior to sequestration will not be amended during FY 1986 in order that research already begun will not be disrupted.

The number of research career program awards will be reduced by 3 for a total of 69 after sequestration with funding of $3,871,000 compared to 72 with funding of $4,044,000 under the appropriation. Only noncompeting awards will be funded. Support for minority biomedical support grants will be reduced by

$20,000 to $440,000 from a level of $460,000 within the appropriation. The decrease in funding will require negotiated reductions of 4.3 percent. Other research grant funding will be reduced by $38,000 to $839,000 after sequestration from the $877,000 provided in the appropriation. Thus, support for ongoing scientific evaluation grants will be reduced accordingly.

The number of full-time training positions supported after sequestration will decrease by 28 for a total of 464 with funding at $10,893,000 compared to the appropriation that provided $11,382,000 for 492 trainees.

Under sequestration funding will be available for 80 R&D contracts at a level of $25,354,000, a reduction of 3 contracts and $1,139,000 from the appropriation that included 83 contracts for $26,493,000.

Support for the Intramural Research Program (IRP) will be reduced by $2,614,000 after sequestration, to a level of $58,182,000 compared to $60,796,000 within the appropriation. In order to achieve this decrease, reductions will be taken in areas such as contractual services, supplies, materials, and equipment, and planned new support contracts will be postponed. In addition, limited hiring restrictions will be imposed.

Research Management and Support will be funded under the sequestration at a level of $15,813,000, a reduction of $711,000 from the appropriation level of $16,524,000. This decrease will be achieved through reductions in areas such as: supplies and materials; the sponsorship of scientific meetings, conferences, symposia and workshops; information dissemination on allergic, immunologic and infectious diseases to health care professionals and the lay public; and, limited hiring restrictions.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

National Institute of General Medical Sciences

Effect of Sequestration

Program/Activity	1986 Appropriation	Sequestration (-)	Available After Sequestering
Research project grants............	$428,524,000	-$18,427,000	$410,097,000
Research centers....	10,219,000	-439,000	9,780,000
Other research......	2,864,000	-123,000	2,741,000
Research training...	57,721,000	-2,482,000	55,239,000
R&D contracts.......	1,263,000	-54,000	1,209,000
Intramural research.	875,000	-38,000	837,000
Research management and support.......	13,299,000	-572,000	12,727,000
Total..........	514,765,000	-22,135,000	492,630,000

Effect of Sequestration

The sequestration will permit the funding of 1,971 noncompeting research project grants at a level of $277,725,000, compared to $290,903,000 within the appropriation. This represents a 2.2 percent increase in average cost over 1985 and a 5.1 percent reduction from historical commitment levels. A total of 963 new and competing renewal research project grants at $131,703,000 will be funded under sequestration compared to $137,621,000 in the appropriation. This represents a .9 percent increase in average cost over 1985 and a 6.4 percent reduction from historical recommended levels. Any grant awarded prior to sequestration will not be amended during FY 1986 in order that research already begun will not be disrupted.

The sequestration will permit the funding of 15 research centers at $9,780,000, compared to 16 research centers at $10,219,000 within the appropriation. This represents a .8 percent reduction from recommended costs compared to a .5 percent reduction in 1985.

The sequestration will require a decrease of 5 grants and $123,000 for other research.

The sequestration will permit the funding of 3,108 full-time training positions at a level of $55,239,000, compared to 3,239 full-time training positions at a level of $57,721,000 within the appropriation.

Research and development contracts, after sequestration, will be funded at $1,209,000, a decrease of $54,000 from the appropriation level.

The sequestration will provide $837,000 for intramural research and $12,727,000 for research management and support, compared to $875,000 and $13,299,000 respectively within the appropriation level. To achieve this 4.3% decrease, reductions in equipment acquisitions, supply purchases, printing orders and site visits will have to take place. Beyond this, the sequestration will require limited hiring restrictions.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

National Institute of Child Health and Human Development

Effect of Sequestration

Program/Activity	Appropriation	Sequestration (-)	Available After Sequestering
Research project grants............	$198,725,000	-$8,546,000	$190,179,000
Research centers....	27,538,000	-1,183,000	26,355,000
Other research......	7,610,000	-327,000	7,283,000
Research training...	13,901,000	-598,000	13,303,000
R&D contracts.......	23,152,000	-996,000	22,156,000
Intramural research.	35,733,000	-1,537,000	34,196,000
Research management and support.......	15,137,000	-651,000	14,486,000
Total...........	321,796,000	13,838,000	307,958,000

Effect of Sequestration

The sequestration will permit the funding of 891 noncompeting research project grants at a level of $125,886,000, compared to $131,543,000 within the appropriation. This represents a 3 percent increase in average cost over 1985 and a 7 percent reduction from historical commitment levels. A total of 481 new and competing renewal research project grants at $64,293,000 will be funded under sequestration, compared to $67,182,000 within the appropriation. This represents a two percent reduction in average costs from 1985 and a 7 percent reduction from historical recommended levels. Any grant awarded prior to sequestration will not be amended during FY 1986 in order that research already begun will not be disrupted.

Research centers would be funded at a level of $26,355,000, compared to $27,538,000 within the appropriation; at both levels 43 centers will be funded. This represents the same average costs as 1985 and a 12 percent reduction from historical recommended levels. This compares with reductions of two percent in 1985.

In other research, sequestration will permit the funding of 105 research career awards at a level of $5,798,000 compared to 110 such awards at $6,059,000 within the appropriation. Minority biomedical research support will be funded at $564,000 and other research related at $921,000, compared to appropriation levels of $589,000 and $962,000 respectively.

In research training, the sequestration level would provide funding for 99 individual NRSAs at a level of $2,440,000, compared with 103 awards and $2,550,000 within the appropriation. For institutional NRSAs, the sequestration level provides for 546 full-time training positions (FTTPs) and $10,863,000, compared with appropriation levels of 571, FTTPs and $11,351,000.

Sequestration will permit funding of 106 research contracts at $22,156,000 as compared to 109 contracts and $23,152,000 within the appropriation.

The sequestration level would provide for $34,196,000 for Intramural research and $14,486,000 for research management and support, compared with $35,733,000 and 15,137,000, respectively, within the appropriation. Reductions will be effected by constraining or eliminating a variety of laboratory and administrative supplies and services, including reductions of consulting services, reducing the scope of intramural projects and clinical actvities, and reducing travel and employee training. Grant and contract management will be reduced, and this will mean fewer site visits in conjunction with review of grant and contract proposals. There will be a reduction in staffing. It is anticipated that the Institute will achieve this reduction through attrition.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

National Eye Institute

Effect of Sequestration

Program/Activity	1986 Appropriation	Sequestration (-)	Available After Sequestering
Research project grants................	$149,337,000	-$6,421,000	$142,916,000
Research centers........	6,100,000	-262,000	5,838,000
Other research..........	2,378,000	-103,000	2,275,000
Research training.......	5,231,000	-224,000	5,007,000
R&D contracts...........	6,649,000	-286,000	6,363,000
Intramural research.....	16,151,000	-695,000	15,456,000
Research management and support...........	5,948,000	-256,000	5,692,000
Construction...........	3,300,000	-142,000	3,158,000
Total...............	195,094,000	-8,389,000	186,705,000

Effect of Sequestration

The sequestration will permit the funding of 783 noncompeting research/project grants at a level of $97,948,000, compared to $102,349,000 within the appropriation. This represents a 2.5 percent increase in average cost over 1985 and a 8.8 percent reduction from historical commitment levels. A total of 358 new and competing renewal research project grants (RPGs) at $44,968,000 will be funded under sequestration, compared to the same number of competing grants at $46,988,000 within the appropriation. This represents a 1.6 percent decrease in average cost from 1985 and a 7.9 percent reduction from historical recommended levels.

Any grant awarded prior to sequestration will not be amended during FY 1986 in order that research already begun will not be disrupted.

The same number of core, center, other research grants and research and development contracts will be supported as at the appropriation level. The sequestration will provide $5,838,000 for 29 core and center grants compared to $6,100,000, the amount included in the appropriation. The other research category will be funded at $2,275,000 rather than the original level of

$2,378,000; 50 awards will be supported in these mechanisms. The required overall reduction of 4.3% will be achieved by adjusting each award proportionally.

Training grants will be reduced from the $5,231,000 appropriated to $5,007,000 after sequestration. No reduction will be made to the 208 full-time-training positions contained in the appropriation but non-stipendary costs will be limited to effect a 4.3% reduction.

There will also be a 4.3% reduction in the amounts available in the NEI construction, renovation, and instrumentation program. The revised levels are $3,158,000 and 18 awards compared to the original appropriation estimates $3,300,000 and 20 awards.

Under the sequestration the intramural research program will be funded at $15,456,000, a 4.3% reduction from the appropriation amount of $16,151,000. This change will be accommodated through attrition and delaying the purchase of supplies and equipment. Similar adjustments will be made in the research management and support activity to continue this program at the sequestration level of $5,692,000. This is a reduction of $256,000.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

National Institute of Environmental Health Sciences

Effect of Sequestration

Program/Activity	1986 Appropriation	Sequestration (-)	Available After Sequestering
Research project grants...............	$56,632,000	$-2,435,000	$54,197,000
Research centers........	15,391,000	- 662,000	14,729,000
Other Research	2,298,000	- 99,000	2,199,000
Research Training.......	8,502,000	-366,000	8,136,000
R & D Contracts.........	54,443,000	-2,341,000	52,102,000
Intramural research	54,169,000	-2,329,000	51,840,000
Research management and support..........	6,043,000	- 260,000	5,783,000
TOTAL	197,478,000	-8,492,000	188,986,000

Effect of Sequestration

The sequestration will permit the funding of 247 noncompeting research project grants at a level of $37,489,000 compared to $39,173,000 within the appropriation. This represents a 4.3 percent increase in average cost over 1985 and a 4.6 percent reduction from historical commitment levels. A total of 111 new and competing renewal research project grants at $16,203,000 will be funded under sequestration, compared to 111 such grants at $16,931,000 within the appropriation. This represents a 1.0 percent decrease in average cost from 1985 and a 4.6 percent reduction from historical recommended levels.

Any grant awarded prior to sequestration will not be amended during FY 1986 in order that research already will begun will not be disrupted.

The sequestration will permit the funding of 15 research centers at $14,729,000, compared to $15,391,000 within the appropriation requiring a downward negotiation of 4.3 percent. The 15 centers were fully funded in 1985.

A total of 36 individual trainees at $679,000 will be funded under sequestration, compared to 38 trainees at $710,000 within the appropriation. A total of 439 institutional trainees at $7,457,000 will be funded under sequestration, compared to $7,792,000 within the appropriation.

The sequestration will permit the funding of 168 research and development contracts at a level of $52,102,000, compared to 178 contracts at $54,443,000 within the appropriation.

Intramural research will be funded at a level of $51,840,000 and 579 FTEs under sequestration, compared to $54,169,000 and 596 FTEs within the appropriation. The reduction in FTEs will be accomplished by adhering to a personnel hiring plan that includes a strict review of any vacancy for priority before recruiting, deletion of a summer employment program, and release of temporary employees if deemed necessary. The dollar reduction will be accomplished by reducing equipment and supply purchases, instituting travel restrictions, and delaying or eliminating facilities engineering services. Protection of direct laboratory research will be a priority.

Research management and support will be funded at a level of $5,783,000 and 81 FTEs, compared to $6,043,000 and 82 FTEs within the appropriation. The reduction in FTEs will be accomplished by adhering to a personnel hiring plan that includes a strict review of any vacancy for priority before recruiting, deletion of a summer employment program, and release of temporary employees if deemed necessary. The dollar reduction will be accomplished by reducing equipment and supply purchases, instituting travel restrictions, and generally tightening controls on other administrative expenses.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

National Institute on Aging

Effect of Sequestration

Program/Activity	1986 Appropriation	Sequestration (-)	Available After Sequestering
Research project grants...........	$ 91,377,000	-$3,929,000	$ 87,448,000
Research centers...	10,396,000	-447,000	9,949,000
Other research.....	6,211,000	-267,000	5,944,000
Research training..	5,507,000	-237,000	5,270,000
R&D contracts......	13,733,000	-591,000	13,142,000
Intramural research	20,915,000	-899,000	20,016,000
Research management and support......	8,352,000	-359,000	7,993,000
Total............	$156,491,000	-$6,729,000	$149,762,000

Effect of Sequestration

The sequestration will permit the funding of 303 noncompeting research project grants at a level of $57,544,000, compared to $60,130,000 within the appropriation. This represents a 7.2 percent increase in average cost over 1985 and a 3.3 percent reduction from historical commitment levels. A total of 193 new and competing renewal research project grants at $29,781,000 will be funded under sequestration, compared to 193 grants at $31,119,000 within the appropriation. This represents a 4.4 percent increase in average cost over 1985 and a 6.8 percent reduction from historical recommended levels. Any grant awarded prior to sequestration will not be amended during FY 1986 in order that research already begun will not be disrupted.

Twelve research centers will be supported under the sequestration at a level of $9,949,000, compared to $10,396,000 within the appropriation. Other research will be supported at a level of $5,944,000, compared to $6,211,000 within the appropriation. The reduction of $267,000 will be achieved by funding 70 rather than 71 research career awards, 11 rather than 14 grants in Other Research, and 5 rather than 6 Minority Biomedical Research Support awards.

The sequestration will permit full funding of $4,448,000 for 195 noncompeting full time equivalent trainees. A total of 35 competing trainees will be supported at a level of $822,000, compared with 45 trainees and $1,059,000 under the appropriation.

The sequestration will also permit the funding of 46 research and development contracts at a level of $13,142,000. This compares with 48 contracts and $13,733,000 contained within the appropriation.

Intramural research will be supported at a level of $20,016,000, compared with $20,915,000 under the appropriation. Research Management and Support will be supported at a level of $7,993,000, compared with $8,352,000 under the appropriation. The reductions in both these activities will be achieved through curtailment of the summer hire program, reduced expenditures for both equipment and supplies, and a reduction in the funds available for staff travel.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

Division of Research Resources

Effect of Sequestration

Program/Activity	1986 Appropriation	Sequestration (-)	Available After Sequestering
Research centers.....	$157,402,000	-$6,768,000	$150,634,000
Other research.......	133,487,000	-5,740,000	127,747,000
Research training....	1,075,000	-46,000	1,029,000
R&D contracts........	5,189,000	-224,000	4,965,000
Research management and support........	8,514,000	-366,000	8,148,000
Total............	305,667,000	-13,144,000	292,523,000

Effect of Sequestration

The sequestration will permit the funding of 185 research center grants, the same number as in the appropriation, at a level of $150,634,000, compared to $157,402,000 within the appropriation. This represents a 1.6 percent decrease in the average cost of a center from 1985, and a 7.9 percent reduction from historical commitment levels. Of the 185 research center grants; 78 will be general clinical research center grants at a level of $86,404,000, compared to $90,286,000 within the appropriation; 61 will be biomedical research technology center grants at a level of $34,100,000, compared to $35,632,000 within the appropriation; and 46 will be laboratory animal sciences and primate research center grants at a level of $30,130,000, compared to $31,484,000 within the appropriation.

In the other research grant mechanism, the sequestration will permit the funding of 887 awards, at a level of $127,747,000; compared to 894 awards, at a level of $133,487,000 within the appropriation. This represents a 4.1 percent decrease in average cost below 1985, and a 7.7 percent reduction from historical commitment levels. This will enable the Division to support 9 animal facility improvement grants, 6 research career awards, 92 minority biomedical research support grants, 21 small business innovative research grants, and 46 other research-related grants. These are the same numbers of awards as in the appropriation. In the Biomedical Research Support (BRS) Program, the sequestration will permit the funding of 713 awards at a level of $91,588,000 as compared to 720 awards at a level of $95,703,000 within the appropriation. Within the BRS Program, the total funds available for the formula grant subactivity will be reduced 4.4 percent. The shared instrumentation grant subactivity will fund 156 grants at a level of $30,459,000, compared to 163 grants at a level of $31,828,000 within the appropriation. This is a 4.3 percent reduction in the number of grants. The Minority High School Student Apprentice subactivity will be unchanged as a result of the sequestration at a level of $1,500,000.

The sequestration will permit the funding of 37 full-time training positions (FTTPs) at a level of $1,029,000, compared to 39 FTTPs at a level of $1,075,000 within the appropriation.

In the research and development contract mechanism, the sequestration will permit the funding of 6 research and development contracts at a level of $4,965,000, compared to $5,189,000 within the appropriation. Thus, an average downward negotiation of 4.3 percent will be necessary on all contract awards.

Any grant awarded prior to sequestration will not be reduced during FY 1986 in order that research already begun will not be disrupted.

The 1986 sequestered level for the research management and support activity will be $8,148,000, a reduction of $366,000 below the appropriated level of $8,514,000. This reduction will be achieved through a limited reduction of other-than-permanent staff. Additional savings of $46,000 are anticipated in personnel services as a result of conservative hiring practices, elimination of summer employment programs, a reduction in paid overtime, and the release of some temporary employees. Of the reduction, $100,000 will be achieved by reducing the workscope of the Research Resources Information Center contract to eliminate some of the information dissemination services it provides to the public. The remaining $130,000 of the reduction will be achieved through travel reductions which will hold employee travel at, or below the 1985 level, reduced purchases of supplies and equipment, and reduced rentals of equipment.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

Fogarty International Center

Effect of Sequestration

Program/Activity	1986 Appropriation	Sequestration (-)	Available After Sequestering
Research centers.....	$1,999,000	-$86,000	$1,913,000
Other research.......	4,622,000	-199,000	4,423,000
Research management and support........	4,930,000	-212,000	4,718,000
Total............	11,551,000	-497,000	11,054,000

Effect of Sequestration

Under research centers, the sequestration will permit the continued funding of the Gorgas Memorial Laboratory at a level of $1,913,000, $86,000 less than within the appropriation.

In other research, the sequestration will permit the funding of 148 fellowships at a level of $4,423,000, compared to 155 fellowships at a level of $4,622,000 within the appropriation. Stipends will remain at their current levels, thus a reduction of 7 fellowships is necessary.

The sequestration in research management and support will permit a funding level of $4,718,000, compared to $4,930,000 within the appropriation. The reduction will be achieved through attrition, however, it will also be necessary to reduce international conference support and international coordination and liaison activities.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

National Library of Medicine

Effect of Sequestration

Program/Activity	1986 Appropriation	Sequestration (-)	Available After Sequestering
Extramural Programs			
Medical Library Assistance...	$7,790,000	-$335,000	$7,455,000
Medical Informatics..........	4,636,000	-199,000	4,437,000
(Med'l Informatics Cong. Incr.)...................	(186,000)	(-8,000)	(178,000)
Total, Extramural..........	12,426,000	-534,000	11,892,000
Intramural Programs.			
Library Operations...........	26,746,000	-1,151,000	25,595,000
(Preservation, library services, acquisition, and cataloging Cong. Incr.)...	(2,008,000)	(-86,000)	(1,922,000)
Lister Hill National Center for Biomedical Communications..............	9,459,000	-407,000	9,052,000
(Unified Med'l Language System Cong. Incr.).......	(1,000,000)	(-43,000)	(957,000)
Toxicology Information.......	3,470,000	-149,000	3,321,000
Total, Intramural..........	39,675,000	-1,707,000	37,968,000
Research Management & Support..	5,707,000	-245,000	5,462,000
Total, NLM................	57,808,000	-2,486,000	55,322,000

Effect of Sequestration

The sequestration level for NLM of $55,322,000 reflects a reduction of $2,486,000 from the appropriation level of $57,808,000.

Intramural programs will decrease by $1,707,000. NLM will reduce the actual acquisition of books and other publications. NLM indexing and cataloging practices, which affect all the nation's medical libraries, will be stored and the backlog of unprocessed materials will increase. Expenditures for collection maintenance and preservation activities will also be reduced. Under consideration are a reduction in hours of service to the public, possibly eliminating weekend and/or evening hours.

Extramural grant programs will be reduced by a total of $534,000. The Integrated Academic Information Management Systems research grants will be reduced by $335,000. Research in Medical Informatics will decrease by $199,000.

Research Management and Support will decrease by $245,000 under sequestration. Staffing for the administrative functions performed by this activity, including grants management, will be reduced through attrition and limited hiring restrictions. Travel and other administrative costs will also be reduced.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

Buildings and Facilities

Effect of Sequestration

Program/Activity	1986 Appropriation	Sequestration (-)	Available After Sequestering
Clinical Center Modernization Project.........................	$ 7,400,000	-$318,000	$ 7,082,000
Laboratory Renovation Program....	2,500,000	-108,000	2,392,000
Repairs and Improvements.........	5,000,000	-215,000	4,785,000
Total........................	$14,900,000	-$641,000	$14,259,000

Effect of Sequestration

The sequestration will permit the continuation of the modernization of the Clinical Center at a level of $7,082,000, compared to $7,400,000 within the appropriation. The rehabilitation of older laboratory buildings will continue at a level of $2,392,000, as compared to $2,500,000 within the appropriation. In addition, funding for the continuation of the program of repairs and improvements will be permitted at a level of $4,785,000, compared to $5,000,000 within the appropriation.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

Office of the Director

Effect of Sequestration

Program/Activity	1986 Appropriation	Sequestration (-)	Available After Sequestering
Acquired Immune Deficiency Syndrome....	$ 70,000	$3,010	$66,990
Academic Research Enhancement Awards.....	10,000	430	9,570
Research Centers at Minority Institutions..	10,000	430	9,570
Office of the Director All Other..............	26,992	1,161	25,831
Total................	116,992	5,031	111,961

Effect of Sequestration

The amount available after the sequestration, $111,961,000, will permit the funding of AIDS research at a level of $66,990,000 compared to $70,000,000 within the appropriation; $19,140,000 for the AREA/RCMI programs compared with $20,000,000; and $25,831,000 for the operation of the Office of the Director compared with $26,992,000.

The new levels for AIDS research and the AREA/RCMI programs will be achieved through reduced awards. The Office of the Director will achieve the sequestration through reductions to personal services and other operating expenses.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

Effect of Sequestration

	1986 Appropriation	Sequestration	FY 1986 Available After Sequestration
Mental Health:			
Research....................	$214,000,000	-9,202,000	$204,798,000
Planning and Demonstration..	12,500,000	-538,000	11,962,000
Research Training...........	18,000,000	-775,000	17,225,000
Clinical Training...........	20,000,000	-860,000	19,140,000
Direct Operations...........	34,675,000	-1,491,000	33,184,000
Protection and Advocacy.....	10,000,000	-430,000	9,570,000
Subtotal.................	309,175,000	-13,296,000	295,879,000
Drug Abuse:			
Research....................	74,000,000	-3,183,000	70,817,000
Research Training...........	1,500,000	-64,000	1,436,000
Direct Operations...........	16,307,000	-701,000	15,606,000
Subtotal.................	91,807,000	3,948,000	87,859,000
Alcoholism:			
Research....................	57,000,000	-2,450,000	54,550,000
Research Training...........	1,500,000	-64,000	1,436,000
Direct Operations...........	11,658,000	-501,000	11,157,000
Subtotal.................	70,158,000	-3,015,000	67,143,000
Buildings and Facilities......	100,000	-4,000	96,000
Program Management............	7,620,000	-328,000	7,292,000
ADAMHA Block Grants...........	490,000,000	-21,070,000	468,930,000
Total, ADAMHA............	$968,860,000	-$41,661,000	$927,199,000

DEPARTMENT OF HEALTH AND HUMAN SERVICES

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute of Mental Health

Effect of Sequestration

Program Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Research:			
Project Grants........	$120,441,000	-5,179,000	$115,262,000
Other Mechanisms......	35,958,000	-1,546,000	34,412,000
Intramural Research...	57,601,000	-2,477,000	55,124,000
Subtotal.........	214,000,000	-9,202,000	204,798,000
Planning & Demonstration	12,500,000	-538,000	11,962,000
Protection & Advocacy...	10,000,000	-430,000	9,570,000
Training:			
Clinical Training.....	20,000,000	-860,000	19,140,000
Research Training.....	18,000,000	-775,000	17,225,000
Subtotal.........	38,000,000	-1,635,000	36,365,000
Direct Operations.......	34,675,000	-1,491,000	33,184,000
Total............	309,175,000	-13,296,000	295,879,000

Effect of Sequestration:

Research:

Extramural:

Project Grants: The 1986 sequester level will support 274 new and competing grants. While research in all priority areas must be reduced, the Institute will still be able to exceed FY 1985 levels of effort in its five major priority areas of schizophrenia, basic brain and behavior research, mental disorders of aging, childhood mental health disorders, and behavioral medicine.

Other Mechanisms: The Institute will be able to maintain its Small Grants program at 96 percent of its originally appropriated level, making 66 awards. The number of new and competing Research Scientist awards will decrease from 52 to 36, but each grant will be awarded at its full level. NIMH will be able to support its originally appropriated level of three new and competing Centers, including one for neuroscience and two for the study of AIDS. The number of Cooperative Agreement awards will also be maintained. To do this, it will be necessary to make some reductions in the average size of new and competing Center and Cooperative Agreement awards.

Research Contracts funds will be reduced by approximately one-fifth, through a combination of reduced award size (narrower scopes of work) and fewer awards. Reductions will relate principally to program evaluation, and to studies on epidemiology and depression.

Intramural: An across-the-board reduction of 4.3 percent was applied to the direct operation portion of the Institute's intramural research laboratories. The principal item of reduction will be equipment, with some deferrals anticipated in the acquisition of supplies. It will not be necessary to close down any laboratories in order to operate within the new level.

Planning and Demonstration: NIMH will make approximately 3 fewer new research demonstration awards under the Planning and Demonstration authority. We expect to fully support the original appropriation level of 47 awards in the adult Community Support program, as well as 28 awards for programs which focus on children. There will be no reduction in scope for programs relating to the homeless.

Protection and Advocacy: Availability of this appropriation is contingent upon passage of authorizing legislation which, as of this date, has not cleared the Congress.

Research Training: The number of trainees supported will be reduced from 851 to 816. The Institute will still be able to award 29 new and competing grants and 55 new fellowships, with emphasis upon training for research in schizophrenia, mental disorders of children and the elderly, molecular genetics, and the behavioral aspects of AIDS.

Clinical Training: Reductions will be proportional between grants and State Manpower Development awards. The total number of new and competing grants awarded will decrease from 190 to 176, but it is anticipated that the Institute will still be able to provide some level of support for all of its priority areas. Within the sequester level, the Institute will still be able to implement a cooperative effort with the Institutes on Alcoholism and Drug Abuse for the training of personnel in the fields of alcohol and drug abuse.

Direct Operations: A reduction of $1,491,000 will be focused primarily upon purchase orders and contracts relating to technical assistance and data gathering activities. The Institute will also seek further economies in its general operating accounts, including travel and the acquisition of supplies and equipment. We do not anticipate the need for a reduction in employment.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTE ON DRUG ABUSE

DRUG ABUSE RESEARCH

Effect of Sequestration

Program Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Research			
Project Grants....	$52,972,000	-$ 2,278,000	$50,694,000
Other Mechanisms..	14,198,000	-611,000	13,587,000
Intramural........	6,830,000	-294,000	6,536,000
Total Research......	74,000,000	-3,183,000	70,817,000
Research Training...	1,500,000	-64,000	1,436,000
Direct Operations...	16,307,000	-701,000	15,606,000
Total...............	91,807,000	-3,948,000	87,859,000

Effect of Sequestration

Research Project Grants: The 1986 sequester will support 131 new and competing grants, the same number as prior to sequestration. The average cost of project grants in FY 1986 will be reduced from $147,100 provided in the FY 1986 appropriation to $140,800. This represents a reduction of approximately $7,000 per grant, or 5 percent from the average costs of grants paid in FY 1985. Because of the ceiling imposed by the FY 1986 authorization level of $74,000,000, it was not possible to implement the Administration's policy of providing a 4 percent increase in average grant costs from FY 1985 levels. This policy would have raised the average cost of FY 1986 grants to $154,100, or $13,000 more than is available after sequestering.

Research Other Mechanisms: The sequestration will eliminate all small grants, reduce funding for one competing center by approximately 40 percent, and reduce funding for new contracts by 5 percent. The contract reduction involves 4 contracts associated with AIDS research which will be reduced by only 4.3 percent.

Intramural Research: The sequestration of funds will result in the delaying or eliminating planned new initiatives in the areas of cocaine and marijuana, delaying or eliminating a study involving PET scanning to investigate metabolism in the brain during narcotic withdrawal, delaying a study of possible biological bases of drug abuse among adolescents, and delaying implementation of new automated data collection techniques.

Research Training: The sequestration of funds will result in a reduction of the number of drug abuse research trainees from 79 provided in the Appropriation to 77.

Direct Operations: The sequestration of funds will result in general reductions in levels of activity throughout the direct operations account; however, most of the reduction will be absorbed from programmatic activities supported with direct operations funds including the printing and distribution of prevention materials and the provision of assistance to State and local officials.

National Institute on Alcohol Abuse and Alcoholism

Effect of Sequestration

	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Research:			
Grants..............	$34,868,000	-$1,499,000	$33,369,000
Other Research.......	13,149,000	-565,000	12,584,000
Intramural...........	8,983,000	-386,000	8,597,000
Subtotal, Research.....	57,000,000	-2,450,000	54,550,000
Research Training......	1,500,000	-64,000	1,436,000
Direct Operations......	11,658,000	-501,000	11,157,000
Total..............	70,158,000	-3,015,000	67,143,000

Research

The sequestration of funds for the regular research grant program will require a reduction in the amounts provided to individual projects. A total of 272 grants, the same number provided by the appropriation, will be awarded at a reduced level. Support for the 172 continuation awards will be reduced by 2 percent and support for the 100 new and competing grants will be reduced by 9 percent from the levels appropriated. Overall, the average grant costs will be reduced from $128,450 to $122,680.

In other extramural research, funding will be reduced for the National Alcohol Research Centers Program, research contracts and Small Business Innovation Research (SBIR) Grants. Funding for the nine existing Centers will be reduced by $416,000, or 4.3 percent, from the appropriated levels. Research contract funds will be reduced by $123,000, eliminating 3 projects on the epidemiology of alcoholism. The SBIR grant program will be reduced by $26,000, leaving an amount equal to 1.25 percent of the extramural research budget, as required by the Small Business Innovation Development Act.

The sequestration of intramural research funds will result in reduced equipment purchases associated with NIAAA's participation in the new nuclear magnetic resonance (NMR) program at NIH, and a postponement of purchases to replace obsolete and unrepairable laboratory equipment.

Research Training

The sequestration of research training funds will require a reduction in the number of trainees supported. Trainees will be reduced to 66, a reduction of 4 percent from the appropriated level of 69.

Direct Operations

In direct operations, the sequestration of funds will reduce funding for the National Clearinghouse for Alcohol Information by 23 percent from the appropriated level. Priority will be given to the maintenance of Clearinghouse capability to respond to inquiries from scientists, clinicians and the public. Other activities of the Clearinghouse, including assistance to the private sector in the development of prevention programs, will be curtailed.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Alcohol, Drug Abuse, and Mental Health Administration

Effect of Sequestration

	1986 Appropriation	Sequestration	1986 Available after Sequestration
Buildings & Facilities...	$100,000	-$4,000	$96,000
Obligations.........	(1,320,000)	(-4,000)	(1,316,000)

Effect of Sequestration

The sequestration of funds for this activity would limit somewhat the availability of funds to maintain the facilities for the ADAMHA intramural research activities.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Alcohol, Drug Abuse, and Mental Health Administration

Effect of Sequestration

	1986 Appropriation	Sequestration	1986 Available after Sequestration
Program Mgmt....	$7,620,000	-$328,000	$7,292,000

Effect of Sequestration

The sequestration of funds will focus on purchase orders and contracts relating to the provision of policy guidance and coordination to the three ADAMHA institutes. Economies in the general operating accounts will also be effected, including travel, supplies, equipment, and printing.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Alcohol, Drug Abuse, and Mental Health Administration

Effect of Sequestration

	1986 Appropriation	Sequestration	1986 Available after Sequestration
Block Grants....	$490,000,000	-$21,070,000	$468,930,000

Effect of Sequestration

The sequestration of funds against the block grant appropriation will result in a decrease of $21,070,000 in discretionary funds available to the States. Because the current allocation formula contains a hold-harmless provision guaranteeing each State at least their 1984 award, a General Counsel opinion was requested on whether the reduction must be applied proportionately to all fifty-seven States or just to the twenty-eight States was receiving an amount in excess of their 1984 award. The decision stated that the authorizing legislation was controlling and, therefore, the total appropriation must be reduced by the required percentage with the allocation formula (as set forth in the Alcohol, Drug Abuse and Mental Health Amendment of 1984) then applied against this lower level. The effect of this decision is that the same 29 States are again held-harmless against receiving less than their 1984 award, leaving the 28 gaining States to bear the effect of sequestration.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

Saint Elizabeths Hospital

Effect of Sequestration

Program Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Availabl After Sequestering
1. Inpatient psychiatric care.....	$67,614,000	$ 1,925,000	$ 65,689,000
(Budget authority).............	(27,772,000)	(1,194,000)	(26,578,000)
2. Inpatient custodial care pending court-ordered outplacement..................	8,864,000	216,000	8,648,000
(Budget authority).............	(---)	(---)	(---)
3. Area D Community Mental Health Center (CMHC) outpatients....................	2,553,000	62,000	2,491,000
(Budget authority).............	(---)	(---)	(---)
4. Outpatient, day care, and outplacement activities, other than Area D CMHC........	5,861,000	169,000	5,692,000
(Budget authority).............	(2,581,000)	(111,000)	(2,470,000)
5. Research.......................	3,734,000	(---)	3,734,000
(Budget authority).............	(---)	(---)	(---)
6. Training.......................	2,665,000	79,000	2,586,000
(Budget authority).............	(1,329,000)	(57,000)	(1,272,000)
7. Program support................	41,632,000	1,269,000	40,363,000
(Budget authority).............	(12,014,000)	(517,000)	(11,497,000)
Total obligations..............	132,923,000	3,720,000	129,203,000
(Budget authority).............	(43,696,000)	(1,879,000)	(41,817,000)

Effect of Sequestration

Sequestration of $3,720,000 from the Hospitals' FY 1986 operating budget will require the following:

o Reduction in the Hospitals' affordable employment ceiling to 3,305 positions by the end of the year. This can be achieved by a full freeze (except professional services) on all hiring through April, 1986 and a selective freeze for the remainder of the year. The reduction represents a 7 percent decrease in the targeted ceiling of 3,558 and a 2 percent decrease from the original affordable ceiling of 3,375. Projected savings are $1.3 million.

- Supply and equipment budgets will be reduced by $1.321 million, representing a 8.43 percent decrease in these areas of the FY 1986 Budget.
- Gramm-Rudman decreases will be partially offset by increased revenues of approximately $.5 million.
- A-76 management studies scheduled for FY 1986 will be cancelled, saving $.6 million.

The general impact of sequestration will be a slight reduction in staff services at all levels, including direct clinical care and patient support services. Programs will not be curtailed. Supervision of supply and equipment purchases will represent deferrals of necessary items to FY 1987. If these reductions are carried over to FY 1987, program reductions will be required if the Hospital's accreditation is to be maintained.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

Public Health Service Management

Effects of Sequestration

Program/Activity	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestration
Health services research/HCTA:			
Program operations	$14,804,000	-$637,000	$14,167,000
Program support	1,638,000	-70,000	1,568,000
Subtotal	16,442,000	-707,000	15,735,000
Health statistics:			
Program operations	43,491,000	-1,870,000	41,621,000
Program support	3,193,000	-137,000	3,056,000
Subtotal	46,684,000	-2,007,000	44,677,000
Adolescent family life	14,689,000	-632,000	14,057,000
Health initiatives:			
Smoking and health	3,526,000	-151,000	3,375,000
Disease prevention and health promotion	3,000,000	-129,000	2,871,000
Physical fitness and sports	1,379,000	-59,000	1,320,000
Subtotal	7,905,000	-339,000	7,566,000
PHS management	18,510,000	-796,000	17,714,000
Total	104,230,000	-4,481,000	99,749,000

Effect of Sequestration - Impact of The Balanced Budget and Emergency Deficit Control Act of 1985

Health Services Research and Health Care Technology Assessment

In FY 1986 this budget activity is being reduced by $707,000 as a result of sequestration. Of this amount, the Program Operations activity will be reduced by $637,000 and the Program Support activity will be reduced by $70,000. The Program Operations activity includes an intramural and extramural research component and a mandate to support the activities of a User Liaison Program which is partially responsible for the dissemination of health services research results. The Program Support activity provides for the planning, coordination, and management of health services research programs.

The FY 1986 target will be met by restructuring the User Liaison Program, reducing ~~travel~~ expenditures and reducing the cost of program planning, coordination and management.

The User Liaison Program currently operates largely through contractor support for meetings to disseminate and discuss health services research as well as for provision of technical assistance to State and local governments. The majority of these funds (60%) are expended on travel and subsistence for individuals from state governments attending these workshops and for support and contractor overhead. Since at least 24 states now have one or more health services research centers in the State, we will restructure the program as a coordination and referral service to enable States and local officials to work with their own resources rather than using a Federal subsidy. State and local personnel will be referred to the research center most geographically convenient and the Federal staff will continue to provide brokering services and technical assistance in lieu of directly sponsoring workshops.

Health Statistics

Program Operations

In FY 1986, this activity is being reduced by $1,870,000 as a result of sequestration.

The National Center for Health Statistics maintains a Nation-wide vital statistics network with the states for the purpose of collecting national data on vital events occurring in the United States on an annual basis. These data are purchased from 54 states/registration areas.

In order to accommodate this reduction the Center will adjust the contract period for the procurement of this data, with no effect on program operations.

Program Support

In FY 1986, NCHS program support is being reduced by $137,000 as a result of sequestration. NCHS will reduce training support and associated travel by approximately 34% to accommodate the sequestration. In addition, plans to purchase equipment will have to be delayed.

Adolescent Family Life

In FY 1986, this account is being reduced by $632,000 as a result of sequestration. This will require reductions in the dollar levels awarded to grantees. The program will continue to maintain the same number of grant awards planned in FY 1986. This approach will allow the program to reach the same number of clients as originally proposed.

Smoking and Health

In FY 1986, this activity is being reduced by $151,000 as a result of sequestration. This reduction will delay a project on the prevalence of cigarette use and use of smokeless tobacco products among teenagers and adolescents.

Disease Prevention and Health Promotion

In FY 1986, this account is being reduced by $129,000 as a result of sequestration. This will result in a reduction in the scope of the Program's national public education program, "Healthy Older People" and in the level of support provided to the Workplace Health Fund cooperative agreement, the National Health Information Clearinghouse, and the United States Preventive Services Task Force.

Physical Fitness and Sports

In FY 1986, this account is being reduced by $59,000 as a result of sequestration. General publications and leadership training aids and materials on physical fitness for youth, abled and disabled, will be continued at a reduced level. -

Public Health Service Management

In FY 1986, this account is being reduced by $796,000 as a result of sequestration. There are several management actions which will be taken to accommodate the reduced funding level. For example, filling of vacancies will be delayed to recoup salary savings; planned travel will be reduced; purchases of equipment to continue the automation plan will be postponed; and training will be postponed or eliminated. A portion of this one-time reduction can be absorbed in FY 1986 because the position of Assistant Secretary for Health has been vacant and the salary, travel and related expenses have not been incurred. These funds will be required in FY 1987.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

Research, Demonstrations and Evaluation Projects
Effect of Sequestration

Program/Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
1. Alternative Payment Systems			
a. New Awards	$ 3,050,000	--	$ 3,050,000
b. Continuations	3,401,996	--	3,401,996
Total	6,451,996	--	6,451,996
2. Hospital Payment			
a. New Awards	2,113,016	$ 258,000	1,855,016
b. Continuations	4,724,943	--	4,724,943
Total	6,837,959	258,000	6,579,959
3. Physician Payment			
a. New Awards	--	--	--
b. Continuations	1,078,756	--	1,078,756
Total	1,078,756	--	1,078,756
4. State Programs for Long-Term Care			
a. New Awards	--	--	--
b. Continuations	1,579,769	--	1,579,769
Total	1,579,769	--	1,579,769
5. Program Analysis, Evaluation and Quality Care[1]			
a. New Awards	4,056,156	--	4,056,156
b. Continuations	7,176,867	--	7,176,867
Total	11,233,023	--	11,233,023
6. Technology and Coverage			
a. New Awards	560,000	560,000	--
b. Continuations	1,626,193	--	1,626,193
Total	2,186,193	560,000	1,626,193
7. Beneficiary Awareness and Prevention			
a. New Awards	500,000	500,000	--
b. Continuations	782,304	--	782,304
Total	1,282,304	500,000	782,304
Summary:			
New Awards	10,279,172	1,318,000	8,961,172
Continuations	20,370,828	--	20,370,828
Total Program	$ 30,650,000 [2]	$ 1,318,000	$ 29,332,000

[1] In the FY 1986 Congressional Budget submission, quality of care studies were associated with program area No. 6, formerly entitled "Quality and Coverage." In FY 1987, quality of care has been combined with Program Analysis/Evaluation and Quality of Care as these are closely related. In the above table, for comparability with FY 1987 figures, we have shifted the quality of care studies into program area No. 5.

[2] Reflects a reduction of $350,000 as required by section 515 of the conference version of the Treasury, Postal Service, and General Government Appropriation Act of 1986, included by reference in the full year continuing resolution for 1986, P.L. 99-190.

Effect of Sequestration

The appropriation provides $10.3 million in new awards. As a result of the sequestering, research, demonstration and evaluation projects totaling $1.3 million would be cancelled in this fiscal year. In particular, planned projects affected are:

-- Studies of selected Medicare and Medicaid coverage issues to determine impact on treatment and service utilization ($560,000);

-- studies which demonstrate and evaluate the extent to which preventive services and patient education efforts prevent, control, delay, or reduce morbidity from chronic diseases and reduce overall costs of health care under Medicare and Medicaid ($500,000); and

-- activities in data collection and research related to the Medicare Prospective Payment System ($258,000).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

ESRD Network Coordinating Councils

Effects of Sequestration

Program/Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
ESRD Network Coordinating Councils	$ 4,837,000	$ 208,000	$ 4,629,000

Effect of Sequestration

The following table displays the use of appropriated funds by function:

Salaries/Fringe Benefits	$ 3,119,865
Travel	280,546
Data	140,273
Consultants	614,299
Other Direct Support	682,017
Total	$ 4,837,000

The categories of Travel, Consultants, and Other Direct Support which includes rent, insurance, and printing would be reduced by $208,000 on a prorata basis.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

Medicare State Certification

Effects of Sequestration

Program/Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
State Certification:			
Medicare Cert.	$ 48,434,000	$ 2,083,000	$ 46,351,000
Gen. Program Spt	3,250,000	140,000	3,110,000

Effect of Sequestration

A 4.3 percent reduction in the Medicare State Certification program will have minimal impact. The reduction will be accommodated through a combination of program efficiencies together with slight reductions to coverage levels for non long-term care facilities that traditionally have experienced few deficiency problems. These include home health agencies, end-stage renal disease facilities and laboratories.

In addition, $140,000 will be reduced from general program support funds which are required for program enhancement activities. Specific procurements to be reduced are:

Procurement	(Dollars in Thousands) Base	Sequester	Impact
o Survey approximately 230 Psychiatric Hospitals	825	35	Minimal impact on surveys to be conducted.
o Conduct Federal Monitoring Surveys of Remaining Certified Psychiatric Hospitals	1,675	72	Minimal impact on surveys to be conducted.
o Survey Improvements in Long-Term Care Facilities and ICFs/MR	500	22	Sequestered amount will have a negligible impact on this procurement.
o Study to establish basis for Improvements in the Psychiatric Hospital Survey Process	250	11	Sequestered amount will have a negligible impact on this procurement.

.DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

Medicare Contractors

Effects of Sequestration

Program/Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Payment Safeguards	$ 231,700,000	$ -8,900,000	$ 222,800,000
Productivity Investments	28,800,000	-12,900,000	15,900,000
Claims Processing	703,000,000	-19,631,000	683,369,000
Total Operating Funds	963,500,000	-41,431,000	922,069,000
Contingency Fund	15,000,000	-645,000	14,355,000
Total Resources	978,500,000	-42,076,000	936,424,000

Effect of Sequestration

Payment Safeguards

Audits of home health agencies, skilled nursing facilities, hospices, end-stage renal disease facilities, as well as non-prospective payment hospitals will be reduced.

Productivity Investments

A reduction of $12,900,000 in Productivity Investments will delay implementation of the following initiatives:

- Implementation of designated regional intermediaries for home health agencies.
- Implementation of the home health screening module which is designed to extract data electronically from forms HCFA-485, and -486 in lieu of review by nurses.
- Implementation of the Health Maintenance Organization (HMO) on-line query system. Implementation this year will be confined to those States with a high concentration of HMO enrollment.
- Changes to the intermediary workload reports, required to verify workload, analyze and track numerous legislative, programmatic, and administrative changes which have been implemented since the FY 1986 budget was developed.
- Testing of standard systems for Part A and Part B.

Claims Processing

A reduction of $19,631,000 in claims processing will result in the following:

- The days work in process will increase from the FY 1985 end of year level from 9 days to 16 days for Part A; and from 11 days to 18 days for Part B.
- The implementation of the Part A Quality Assurance activity will be delayed. This activity ensures the correctness of paid claims.
- Modifications to physician identification (licensure table) which enables the PROs to monitor admission patterns and patterns of care will be delayed.
- Updating of the Provider Statistical and Reimbursement (PS&R) system will be delayed. The system produces reports used in cost report preparation and cost settlement and eliminates the need for providers to maintain logs.

Contingency Fund

The amount available for unanticipated workload increases and operating costs will be reduced by $645,000.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH CARE FINANCING ADMINISTRATION

Administrative Costs

Effect of Sequestration

Program Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Administrative Costs	$215,068,000	$ 9,248,000	$ 205,820,000

Sequestration of funds in the Administrative Costs budget will impact on HCFA's ability to effectively and efficiently accomplish its program objectives. The major object classes affected will be travel, printing, and contracts. These object classes will be reduced approximately 25 percent below the FY 1986 appropriation. The sequestration will result in reduced efforts in the following areas:

- Audits and reviews to monitor and evaluate performance of Medicare Contractors, State Medicaid Agencies, Peer Review Organizations, and State Survey Agencies will be reduced.
- Certain contracts that assist HCFA in managing its programs will not be awarded. For example, contracts were cancelled that would have funded (1) oversight reviews of third party collection efforts in targeted States; (2) a national survey to measure the effect of the Agency's Medicare Secondary Payer cost avoidance initiatives, and (3) the development of Medicaid caseload models that would have enabled the Agency to improve Medicaid actuarial estimates.
- Initiatives to improve the Agency's automated data processing capabilities will be reduced. For example, (1) redesign efforts involving the Health Insurance System will either be reduced or curtailed, (2) planned purchases of microcomputers, word processors, and other automated data processing (ADP) equipment will be reduced, and (3) initiatives to provide training to microcomputer users throughout the Agency will be reduced.
- Training initiatives designed to provide supervisory and management level training to employees will be reduced.
- The purchase of operating supplies, the replacement of outdated equipment, and efforts to renovate existing space will be reduced.
- A wide variety of publications and issuances that keep providers, contractors, and the beneficiary community abreast of the policies and procedures affecting the Medicare and Medicaid programs will either not be published or will be published in reduced amounts.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SOCIAL SECURITY ADMINISTRATION

Supplemental Security Income

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Payments to Trust Funds for Administrative Costs....	$1,010,507,000	-$32,669,000	$977,838,000

Effect of Sequestration

The only activity subject to sequestration is Payments to the Trust Funds for Administrative Costs. The funds appropriated for this activity represent an estimate of the amount that the General Fund will have to pay the Social Security Trust Funds for expenses to be incurred by SSA in administering the SSI program, a non-trust fund program. Since 4.3 percent of all SSA resources available for administration in FY 1986 are to be sequestered, resources for the administrative expenses of the SSI program also will be sequestered at this rate.

The derivation of the funds subject to sequestration and the sequestered amount is shown below:

	Funds Subject to Sequestration
1986 Appropriation for Payments to Trust Funds for Administrative Costs...........	$1,010,507,000
Less SSI share of funds for Disability State agencies which are exempt from sequestration...........................	-250,767,000
Sub-total............................	$759,740,000
Sequester (4.3% x $759,740,000)........... =	$32,669,000

The sequestration of SSI administrative funds will not require reductions-in-force or furloughing of Federal employees. The reductions will be taken from the following:

--Overtime and non-ceiling employment

--The SSI portion of the $30 million added by Congress to SSA's administrative budget for FY 1986.

--Other objects of expenditure (for example, travel, training, equipment replacement, supplies and printing).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

SOCIAL SECURITY ADMINISTRATION

Assistance Payments

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Research and Evaluation...	$2,925,000	-$126,000	$2,799,000
Federal Administration....	$33,932,000	-$1,459,000	$32,473,000

Effect of Sequestration

Grants to States and other jurisdictions for AFDC and related purposes are exempted from sequestration under the Balanced Budget and Emergency Deficit Control Act of 1985. The funds for Research and Evaluation will be reduced by $126,000 and the funds for the Federal Administration activity will be reduced by $1,459,000 in 1986. Each of these reductions is 4.3 percent of the appropriation for the activity. The effect of the sequester order on these activities is summarized below.

Research and Evaluation funds will be reduced by $126,000 from $2,925,000 to $2,799,000 in 1986. The reduction will be achieved by reducing the planned budget for several grants to be awarded in 1986.

After taking into account expected savings in 1986 from lower than budgeted payroll expenses that will be used to offset non-payroll increases, the reduction of $1,459,000 will be obtained through the following actions:

--reducing expenditures for travel, conferences and meetings,
--modifying plans to integrate and expand automatic data processing and office automation capabilities in the Office of Family Assistance,
--cancelling funds for two consultant service contracts planned for 1986, and
--reducing other expenditures for printing, interagency agreements and other administrative contracts.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SOCIAL SECURITY ADMINISTRATION

Special Benefits for Disabled Coal Miners

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Federal Administration......	$6,519,000	-$280,000	$6,239,000

Effect of Sequestration

Although automatic benefit increases for special benefits for disabled coal miners (black lung program) are subject to sequestration under the Balanced Budget and Emergency Deficit Control Act of 1985, there is no sequestration in FY 1986 since there will be no automatic benefit increase. The black lung benefits increase only when there are increases in the salaries of Federal employees.

Federal administrative expenses for the Social Security Administration to administer the black lung program in fiscal year 1986 will be reduced by 4.3 percent, or $280,000. The changes in full-time equivalents and workyears necessary to achieve the reduction are shown in the table below:

	Appropriation	Current Estimates	Changes
Full-time equivalents.....	188	188	--
Workyears.................	199	190	-9

SSA expects to achieve the reduction in Federal administrative expenses without reduction-in-force or furloughs and without adversely affecting the payments of monthly benefit payments to disabled coal miners, to their widows and certain other dependents. SSA will attempt to absorb part of the $280,000 reduction in Federal administrative expenses by stressing the need to improve employee productivity. This effort is targeted to save $172,000 and reduce budgeted workyears from 199 to 190. The reductions in work-years will be taken in overtime and non-ceiling employment rather than in FTE's. SSA expects to save the balance of $108,000 from lower salary expenses based on 1985 actual experience, and preliminary information for 1986, which shows that payroll costs for 1986 will be lower than budgeted.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

SOCIAL SECURITY ADMINISTRATION

Low Income Home Energy Assistance

Effect of Sequestration

Program/ Activity	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Energy Assistance Block Grant......	$2,097,765,000	-$90,204,000	$2,007,561,000
Federal Administration...	2,235,000	-96,000	2,139,000
Total, Energy Assistance.......	$2,100,000,000	-$90,300,000	$2,009,700,000

Effect of Sequestration

Pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985, P.L. 99-177, the $2,097,765,000 for the Low Income Home Energy Assistance program grants will be reduced by $90,204,000, and the $2,235,000 for Federal administration of the program grants will be reduced by $96,000 in FY 1986. Both reductions represent 4.3 percent of the total for each activity in the appropriation.

Energy Assistance Block Grant

Based on advice from the Office of General Counsel, the grant reduction of $90,204,000 required by the Balanced Budget and Emergency Deficit Control Act of 1985 will be treated as a reduction in the appropriation and will be distributed according to the allocation formula for the Low Income Home Energy Assistance program (LIHEAP) in Section 2604 of the Omnibus Budget Reconciliation Act of 1981. This language directs that no State shall receive less in FY 1986 than it would have received in FY 1984. This "hold-harmless" provision prevents the Social Security Administration from making further reductions to the program grants of twenty-three States, as long as the appropriation remains above $1,975,000,000.

Thus, the $90,204,000 reduction must be distributed over the remaining 27 States, the District of Columbia, Puerto Rico and the territories. Grants to the remaining 27 States, the District of Columbia, Puerto Rico and the territories will decrease by percentage amounts ranging from 4.3 percent to 11.7 percent. Grants to Indian tribes generally will decrease by the same percentage as does the allotment to the States in which the tribe is located.

Because of the flexibility given to grantees under the Low-Income Home Energy Assistance program to use the block grant, it is impossible to forecast the specific effects of sequestration.

Federal Administration

Funds for SSA to administer the LIHEAP program in 1986 will be reduced by $96,000 from $2,235,000 to $2,239,000. SSA plans to achieve this reduction by reducing the amounts to be allocated for contracts and interagency agreements.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SOCIAL SECURITY ADMINISTRATION

Limitation on Administrative Expenses

Effect of Sequestration

	Budget Authority		
	FY 1986 Appropriation and Other Resources Available	Sequestration	FY 1986 Resources Available After Sequestration
Contingency Reserve.........	$145,000,000	$6,235,000	$138,765,000
ADP/Telecommunications			
1986 Appropriation..........	182,939,000	7,866,000	175,073,000
Carry-over funds...........	217,103,000	4,406,000	212,697,000
Sub-total...............	$400,042,000	$12,272,000	$387,770,000
All Other			
1986 Appropriation..........	3,664,547,000	125,850,000	3,538,697,000
Disability State Agencies..	(741,206,000)	-0-	($741,206,000)
Carry-over funds (construction)............	10,031,000	-0-	10,031,000
Sub-total...............	$3,674,578,000	$125,850,000	$3,548,728,000
Total................	$4,219,620,000	$144,357,000	$4,075,263,000

Since the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriation Act, 1986 (Public Law 99-178), included specific levels in the Limitation account for the contingency reserve and ADP/telecommunications, it has been determined that a 4.3 percent reduction must be taken in each of the following areas:

	Reduction
--Contingency reserve..................	$6,235,000
--ADP/telecommunications...............	$12,272,000
--All other Federal Administration.....	$125,850,000

Contingency Reserve

The reduction in the contingency reserve (which is available only to meet workloads and disability State agency costs that exceed the budget estimates, and for certain other purposes) is not of a sufficient magnitude to constitute any threat to program operations and service to the public.

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ADP Telecommunications

For ADP/telecommunications, funds are appropriated on a no-year basis. The funds subject to sequestration and the sequestered amount, were derived as follows:

		Funds Subject to Sequestration
1986 appropriation..................		$182,939,000
Unobligated funds carried over from previous years...............		217,103,000
Less unobligated balance anticipated at end of FY 1986.....		-114,641,000
Sub-total......................		$285,401,000
Sequester (4.3 % x $285,401,000)....	=	$12,272,000

The Social Security Administration (SSA) does not anticipate that the reduction in ADP/telecommunications will impair the systems modernization plan (SMP), since the agency has substantial carry-over balances available to finance the necessary hardware, software and other services needed for the SMP.

Other Federal Administration

The "all other" category includes resources for the Disability State agencies, salaries and expenses for the Federal staff of the Social Security Administration, and no-year construction funds unobligated at the end of FY 1985. Funds appropriated for the Disability State agencies ($741,206,000) are not subject to sequestration because of the language in Section 256 (b)(3) of the Balanced Budget and Emergency Deficit Control Act of 1985 (P.L. 99-177).

The derivation of the funds subject to sequestration and the sequestered amount in the "all other" category is shown below:

		Funds Subject to Sequestration
1986 appropriation..................		$3,664,547,000
Unobligated funds carried over from previous year (construction)......		10,031,000
Less Disability State agency funds appropriated in FY 1986...........		-741,206,000
Less unobligated balances anticipated at end of FY 1986 in construction...................		-6,647,000
Sub-total......................		$2,926,725,000
Sequester (4.3% x $2,926,725,000)...	=	$125,850,000

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The reductions in the "Federal administration" category will not require reductions-in-force, or furloughing of Federal employees. In the table below we have compared the full-time equivalents (FTE's) and workyears available under the 1986 current estimates before and after sequestration.

	1986 Before Sequestration	1986 After Sequestration	Difference
FTE's....................	77,349	76,169	-1,180
Non-ceiling employment...	1,793	1,069	-724
Overtime.................	3,113	1,775	-1,338
Total workyears........	82,255	79,013	-3,242
% Overtime to Total....	3.8%	2.2%	-1.6%

From this reduction in workyears and other reductions in personnel compensation and benefits SSA will be able to meet $95,148,000 of the $125,850,000 sequester.

Thirty-million dollars of the required reduction will be obtained by maintaining FTE's at the 1986 President's budget level. SSA does not anticipate that this action will result in any diminution of service to the public, in terms of processing times, waiting times in district offices, or payment accuracy. We will be reporting to the Appropriations Committee quarterly on indicators of service to the public, as requested in House Report 99-289. The balance of the FTE reduction (180 FTE's) is due to SSA's experience in underrealization of taxation-of-benefit workloads in FY 1985, when 12.5 million inquiries were projected in the budget but only 1.4 million were received. Based on our experience in FY 1985, we have reduced estimated requirements for taxation of benefit work in FY 1986.

Through the reductions in overtime and non-ceiling employment, SSA will obtain $65,148,000 of the total sequester. Overtime will be reduced from 3,113 to 1,775 workyears. Should the reduction in overtime lead to rising backlogs, or processing times, consideration will be given to tapping the contingency reserve to increase workyears. The reduction in non-ceiling employment (724 workyears) will be taken in SSA's stay-in-school and summer aide programs and will reduce the size of these programs by approximately 50 percent.

The remainder of the reduction ($30,702,000) will be obtained through reductions in other objects of expenditure--for example, travel, training, equipment replacement, supplies and printing.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF REFUGEE RESETTLEMENT

Refugee and Entrant Assistance

Effect of Sequestration

	FY 1986 Appropriation	Sequestration(-)	FY 1986 Available After Sequestration
State Administered Programs			
Cash/Medical/Administration (CMA)	$270,756,000	$11,643,000	$259,113,000
Social Services	71,700,000	3,083,000	68,617,000
Total, State Administered Programs	342,456,000	14,726,000	327,730,000
Voluntary Agency Programs	4,000,000	172,000	3,828,000
Targeted Assistance	50,000,000	2,150,000	47,850,000
Education Assistance for Children	16,600,000	714,000	15,886,000
Federal Administration	6,405,000	275,000	6,130,000
Preventive Health	8,400,000	361,000	8,039,000
Total, Refugee and Entrant Assistance	$427,861,000	$18,398,000	$409,463,000

Effect of Sequestration

1. State Administered Programs - CMA

The FY 1986 budget for Cash and Medical Assistance (CMA) is reduced by $11,643,000 as the result of sequestering under Gramm-Rudman-Hollings. In order to achieve this level of savings, ORR will institute a new program policy, effective March 1, 1986, whereby the special CMA reimbursement will be limited to the initial thirty-one months instead of thirty-six months of assistance paid to refugees under the programs of Aid to Families with Dependent Children (AFDC), Medicaid (Title XIX), General Assistance (GA), General Medical Assistance (GMA), and Supplemental Security Income (SSI). No refugee will lose benefits as a result of this change; only the proportion of assistance costs borne by the Federal government will revert from the special 100 percent rate to the standard rate for each program. Aid to unaccompanied minors will not be affected by the new policy. Special Refugee Cash Assistance (RCA) will continue to be available for a refugee's first eighteen months in the country, but reimbursements for General Assistance (GA) paid beyond this period will be limited to months nineteen to thirty-one. This will have no effect on either the refugee's GA eligibility or benefit level. Related State administrative costs will be reduced correspondingly.

Effect of Sequestration - (Contd.)

2. State Administered Programs - Social Services

Gramm-Rudman-Hollings sequestering will reduce funding for social services by $3,803,000. Funding for the refugee program by a series of continuing resolutions over the past three fiscal years in the face of declining refugee flows has resulted in a level of support for social services (and other discretionary activities) that exceeds historical per capita amounts. As a result there will be no substantial effects from the reduction.

3. Voluntary Agency Programs

The reduction required by Gramm-Rudman-Hollings sequestering is $172,000. By reducing the maximum match available to non-profit organizations from $1,000 per refugee to an average of $957 per refugee, the program will be able to serve 4,000 refugees as intended.

4. Targeted Assistance

The reduction due to Gramm-Rudman-Hollings sequestering on FY 1986 Targeted Assistance is $2,150,000. Since FY 1985 and earlier appropriations are anticipated to carry most, if not all, projects through the end of March 1987, the reduced level of funding will be adequate to meet remaining needs.

5. Education Assistance

Gramm-Rudman-Hollings sequestering will reduce funding for education assistance for children by $714,000. However, due to of past progress towards building capacity in local educational systems and reduced refugee admissions, ORR believes that this level of funding will respond to current demand.

6. Federal Administration

The reduction required by Gramm-Rudman-Hollings for the Federal Administration activity is $275,000. The amount will be absorbed through consolidating Regional Offices and reducing administrative costs.

7. Preventive Health

The $361,000 sequestration will reduce funding available for grants to States for health assessments. The planned level of health assessments for secondary migrants will be reduced by 3,900 to a total of 15,300 with the numbers of health screening overseas and primary health assessments through the States being maintained at their budgeted levels.

Refugee and Entrant Assistance

Summary State Table
(000)

STATE	1986	1986 REVISED	GRAMM-RUDMAN-HOLLINGS REDUCTION
TOTAL	$ 427,861	$ 409,463	$ 18,398
Alabama	764	746	18
Alaska	---	---	---
Arizona	2,958	2,923	35
Arkansas	410	400	10
California	163,320	153,739	9,581
Colorado	4,017	3,881	136
Connecticut	4,323	4,224	99
Delaware	48	46	2
Dist. of Columbia	7,007	6,734 (1)	273
Florida	25,750	24,659	1,091
Georgia	4,947	4,770	177
Guam	---	---	---
Hawaii	2,860	2,771	89
Idaho	1,010	995	15
Illinois	16,410	15,978	432
Indiana	694	665	29
Iowa	4,141	4,071	70
Kansas	4,007	3,838	169
Kentucky	668	652	16
Louisiana	3,029	2,944	85
Maine	1,216	1,192	24
Maryland	4,199	4,052	147
Massachusetts	19,647	18,823	824
Michigan	4,712	4,499	213
Minnesota	14,074	13,465	609
Mississippi	681	671	10
Missouri	2,044	1,960	84
Montana	262	248	14
Nebraska	696	676	20
Nevada	684	664	20
New Hampshire	539	532	7
New Jersey	5,220	4,998	222
New Mexico	479	463	16
New York	42,116	41,257	859
North Carolina	1,736	1,696	40

Refugee and Entrant Assistance

Summary State Table (continued)
(000)

STATE	1986	1986 REVISED	GRAMM-RUDMAN-HOLLINGS REDUCTION
North Dakota	596	583	13
Ohio	4,871	4,641	230
Oklahoma	1,870	1,818	52
Oregon	10,591	10,389	202
Pennsylvania	8,825	8,125	700
Rhode Island	3,267	3,119	148
South Carolina	544	533	11
South Dakota	266	259	7
Tennessee	1,339	1,292	47
Texas	11,583	11,221	362
Utah	2,951	2,855	96
Vermont	584	574	10
Virginia	9,320	9,055	265
Washington	22,930	22,331	599
West Virginia	99	95	4
Wisconsin	3,451	3,241	210
Wyoming	106	100	6

(1) Includes $100,000 of unobligated funds related to consultant services.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF HUMAN DEVELOPMENT SERVICES

Social Services Block Grant

Effect of Sequestration

	FY 1986 Appropriation	Sequestration(-)	FY 1986 Available After Sequestering
Social Services Block Grant	$2,700,000,000	-$116,100,000	$2,583,900,000

Effect of Sequestration

For the Social Services Block Grant, sequestering would result in a reduction of $116,100,000 from the Fiscal Year 1986 appropriation of $2,700,000,000. Each State's allotment would be 4.3 percent less than it would have been under the appropriation of $2,700,000. States would have complete flexibility in determining the areas where reductions would be sustained and would continue to have flexibility to transfer funds among various block grants received from the Federal government.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF HUMAN DEVELOPMENT SERVICES

Human Development Services

	1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Administration for Children, Youth and Families			
Head Start	$1,087,059,000	- $46,744,000	$1,040,315,000
Child Abuse State Grants	12,000,000	- 559,000	11,441,000
Child Abuse Discretionary Activities	14,000,000	- 559,000	13,441,000
Runaway and Homeless Youth	23,250,000	- 1,000,000	22,250,000
Family Violence	2,500,000	- 107,000	2,393,000
Dependent Care Planning and Development	5,000,000	- 215,000	4,785,000
Subtotal, Administration for Children, Youth and Families	1,143,809,000	- 49,184,000	1,094,625,000
Administration on Aging			
Supportive Services and Centers	265,000,000	- 11,395,000	253,605,000
Nutrition Congregate Meals	336,000,000	- 14,448,000	321,552,000
Home-delivered Meals	67,900,000	- 2,920,000	64,980,000
Grants to Indian Tribes	7,500,000	- 322,000	7,178,000
Research, Training and Discretionary Projects	25,000,000	- 1,075,000	23,925,000
Federal Council on Aging	200,000	- 9,000	191,000
Subtotal, Administration on Aging	701,600,000	- 30,169,000	671,431,000

	1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Administration on Developmental Disabilities			
Basic State Grants	$53,400,000	- $2,296,000	$51,104,000
Protection and Advocacy . . .	14,600,000	- 628,000	13,972,000
Special Projects	2,800,000	- 120,000	2,680,000
University Affiliated Facilities. . . .	9,600,000	- 413,000	9,187,000
Subtotal, Administration on Developmental Disabilitis	80,400,000	- 3,457,000	76,943,000
Administration for Native Americans			
Financial Assistance Grants	27,300,000	- 1,174,000	26,126,000
Training and Technical Assistance	1,000,000	- 43,000	957,000
Research, Demonstration and Evaluation	700,000	- 30,000	670,000
Subtotal, Administration for Native Americans	29,000,000	- 1,247,000	27,753,000
Program Direction (Salaries and Expenses)	61,113,000	- 2,628,000	58,485,000
Total, Human Development Services	$2,015,921,000	- $86,685,000	$1,929,236,000

Effect of Sequestration

For Human Development Services, sequestering would result in a reduction of $86,685,000 from the Fiscal Year 1986 appropriation of $2,015,921,000.

Administration for Children, Youth and Families

For the Administration for Children, Youth and Families sequestering would result in a reduction of $49,184,000 from the Fiscal Year 1986 appropriation of $1,143,809,000.

Head Start - Sequestering would reduce the Fiscal Year 1986 appropriation of $1,087,059,000 by $46,744,000. This action eliminates the $12 million increase for Head Start in the original 1986 appropriation. Under the appropriated level 448,250 children would be served. No reductions in the number of children currently being served will occur during this program year. However, if the full reduction were made permanent, it would reduce the number of children served in future years. Reductions in activities in the 1986 funding cycle will be minimized through the reallocation of program improvement funds to maintain service levels, the redirection into services of funds generated through management efficiencies, and small reductions in grantee budget areas not affecting the number of children served, e.g. administrative costs. In addition, a 4.3% reduction will be made in the discretionary account, but the legal requirement that $25 million be spent on training and technical assistance will result in the entire reduction being taken from the research, demonstration, evaluation and special handicapped programs.

Child Abuse State Grants - Sequestering would reduce the Fiscal Year 1986 appropriation of $12,000,000 by $559,000. In order to comply with the authorizing statute, the total amount sequestered would be taken from grants for "Baby Doe" activities.

Child Abuse Discretionary Activities - Sequestering would reduce the Fiscal Year 1986 appropriation of $14,000,000 by $559,000. In order to comply with the authorizing statute, the total of $559,000 would be taken from discretionary grants for the prevention of sexual abuse. The average grant award for these activities would be reduced and it is likely that fewer grants would be made than originally planned.

Runaway and Homeless Youth - Sequestering would reduce the Fiscal Year 1986 appropriation of $23,250,000 by $1,000,000. It will have no adverse effect on the level available for centers, or the national toll-free communication system. Centers would serve 80,000 youth and their families, and 260,000 persons would be served through the national toll-free communication system. Fewer research and demonstration grants would be supported.

Family Violence - Sequestering would reduce the Fiscal Year 1986 appropriation of $2,500,000 by $107,000. Grants made in 1986 will be less per State than originally planned.

Dependent Care Planning and Development - Sequestering would reduce the Fiscal Year 1986 appropriation of $5,000,000 by $215,000. No grants have been made in this new categorical program. In 1986, each State's grant will be reduced proportionally.

Administration on Aging

For the Administration on Aging, sequestering would result in a reduction of $30,169,000 from the Fiscal Year 1986 appropriation of $701,600,000.

Supportive Services and Centers - Sequestering would reduce the Fiscal Year 1986 appropriation of $265,000,000 by $11,395,000. The levels of service supported by the appropriated level would be reduced by slightly more than 4 percent. Every effort will be made to minimize reductions in service levels through management improvements and cost efficiencies.

Nutrition Services - Sequestering would reduce the fiscal year appropriation of $336,000,000 for congregate meals by $14,448,000 and the appropriation of $67,900,000 for home-delivered meals by $2,920,000. The levels of service would be reduced by slightly more than 4 percent. Every effort will be made to minimize meal reductions through management improvements and cost efficiencies.

Grants to Indian Tribes - Sequestering would reduce the Fiscal Year 1986 appropriation of $7,500,000 by $322,000. All applicants who meet the requirements of the Older Americans will be funded. It is estimated that the current average grant award of $60,000 may be reduced by about $2,000.

Research, Training, and Discretionary Projects - Sequestering would reduce the Fiscal Year 1986 appropriation of $25,000,000 by $1,075,000. This reduction would not substantially affect these discretionary initiatives. It would not be possible to maintain all discretionary areas at 1985 levels of support but with continued careful analysis of award selection, it is expected that projects of the highest quality would continue to be supported. The average grant award would be slightly reduced.

Federal Council on Aging - Sequestering would reduce the Fiscal Year 1986 appropriation of $200,000 by $9,000. Because the Council did not spend all of its 1985 appropriation, sequestration in 1986 would have no adverse effect.

Administration on Developmental Disabilities

For the Administration on Developmental Disabilities, sequestering would result in a reduction of $3,457,000 from the Fiscal Year 1986 appropriation of $80,400,000.

Basic State Grants - Sequestering would reduce the Fiscal Year 1986 appropriation of $53,400,000 by $2,296,000. Because the 1986 appropriation included increased funds, reductions due to sequestering would still allow States to maintain service levels to clients that were provided in Fiscal Year 1985. Because the authorizing statute prescribes minimum allotments for some States and territories, other States would sustain a reduction in excess of 4.3 percent.

Protection and Advocacy - Sequestering would reduce the Fiscal Year 1986 appropriation of $14,600,000 by $628,000. It is expected that States would be able to continue to provide levels of service comparable to those provided in Fiscal Year 1985. Because the authorizing statute prescribes minimum allotments for some States and territories, other States would sustain a reduction in excess of of 4.3 percent.

Special Projects - Sequestering would reduce the Fiscal Year 1986 appropriation of $2,800,000 by $120,000. This reduction will result in a slightly reduced average amount per grant.

University Affiliated Facilities - Sequestering would reduce the Fiscal Year 1986 appropriation of $9,600,000 by $413,000. All existing University Affiliated Facilities and satellite centers would be supported at 1985 levels. In addition projects related to the community integration focus of the Developmental Disabilities Act of 1984 will be supported at levels slightly below those originally planned.

Administration for Native Americans

For the Administration on Native Americans, sequestering would result in a reduction of $1,247,000 from the fiscal year 1986 appropriation of $29,000,000. Sequestering would reduce the Fiscal Year 1986 appropriation for Financial Assistance Grants of $27,300,000 by $ 1,174,000. Approximately 209 grants would be awarded, 10 fewer than originally estimated under the appropriation. Sequestering would reduce the fiscal year 1986 appropriation of $1,000,000 for Training and Technical Assistance by $43,000. The reduction would result in a slightly reduced amount per grant. Sequestering would reduce the Fiscal Year 1986 appropriation of $700,000 for Research, Demonstration and Evaluation by $30,000. The reduction would result in a slightly reduced amount per grant.

Program Direction (Salaries and Expenses)

Sequestering would reduce the Fiscal Year 1986 appropriation of $61,113,000 by $2,628,000. At the reduced level, an FTE level of 1,125 could be supported, as opposed to 1,146 FTE supported by the 1986 appropriation. Travel would be reduced by 21 percent from the 1985 level and proportionate reductions would be made in other object classes.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF HUMAN DEVELOPMENT SERVICES

Family Social Services

Effect of Sequestration

	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Foster Care . . .	$ 507,641,000	- $ 6,061,000	$ 501,580,000
Adoption Assistance . . .	41,948,000	- 557,000	41,391,000
Child Welfare Services	207,000,000	- 8,901,000	198,099,000
Child Welfare Training	3,823,000	- 165,000	3,658,000
Child Welfare Research and Demonstration . .	11,825,000	- 508,000	11,317,000
Adoption Opportunities . .	5,000,000	- 215,000	4,785,000
Total, Family Social Services	$777,237,000	- $16,407,000	$760,830,000

Effect of Sequestration

For Family Social Services, sequestering would result in a reduction of $16,407,000 from the Fiscal Year 1986 appropriation of $777,237,000.

Foster Care - Sequestering would reduce the Fiscal Year 1986 appropriation of $507,641,000 by $6,061,000. No Federal matching will be available to States for those increases in their maintenance payments which are the result of increases in their Foster Care rates effective at any point in Fiscal Year 1986, as stipulated by the special rules for this program in the Balanced Budget Act. Only States which grant rate increases would be affected. It is not expected that any fewer children will be served as a result.

Adoption Assistance - Sequestering would reduce the Fiscal Year 1986 appropration of $41,948,000 by $557,000. No Federal matching will be available to States for those increases in their maintenance payments which are the result of increases in their Foster Care rates effective at any point in Fiscal Year 1986, as stipulated by the special rules for this program in the Balanced Budget Act. Only States which grant rate increases would be affected. It is not expected that fewer children or families would be served as a result.

Child Welfare Services - Sequestering would reduce the Fiscal Year 1986 appropriation of $207,000,000 by $8,901,000. This lower amount will be distributed according to the current formula for determining grants, under which each State first receives a base amount of $70,000. This aspect of the formula will result in differential percentage reduction among the States. Nonetheless, because the 1986 appropriation included increased funds, reductions due to sequestering would have minimal impact on the number of families served and the level of services provided, compared to current levels of services.

Child Welfare Training - Sequestering would reduce the Fiscal Year 1986 appropriation of $3,823,000 by $165,000. The original 1986 plan included 75 projects. Sequestration would result in a slightly reduced average amount per grant.

Child Welfare Research and Demonstration - Sequestering would reduce the Fiscal Year 1986 appropriation of $11,825,000 by $508,000. The reduction will result in a slightly reduced average amount per grant.

Adoption Opportunities - The Fiscal Year 1986 appropriation of $5,000,000 is $3,000,000 more than the Fiscal Year 1985 appropriation. Sequestering would reduce this amount by $215,000. The reduction would result in a slightly reduced average amount per grant.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF HUMAN DEVELOPMENT SERVICES

Work Incentive

Effect of Sequestration

	FY 1986 Appropriation	Sequestration (-)	FY 1986 Available After Sequestering
Grants to States........	$212,000,000	-$9,116,000	$202,884,000
Program Direction and Evaluation	8,000,000	-344,000	7,656,000
Total, Work Incentive............	$220,000,000	-$9,460,000	$210,540,000

Effect of Sequestration

For the Work Incentive account, sequestration will reduce the appropriation of $220,000,000 by $9,460,000.

Grants to States for the remainder of the year will be reduced by $9,116,000, an approximate 8 percent reduction since the 4.3 percent sequestration came five months into the fiscal year.

Due to the sequestration, WIN will not register approximately 27,800 recipients as part of the universal work requirement, and will reduce "entered unsubsidized employments" by about 5,600. These reductions will occur based on a 10 percent reduction in State and local line staff, or 185 individuals. However, program staff will continue to assist welfare recipients into unsubsidized employment and to gain economic independence.

In the Program Director and Evaluation activity, which funds Federal staff in the National and Regional Offices, the $344,000 sequestration will be absorded by reducing technical assistance and training activities, research and development special projects, and the non-personnel services portion of Federal salaries and expenses.

DEPARTMENT OF HEALTH OF HUMAN SERVICES

Office of Community Services

Community Services Block Grant Program

Effect of Sequestration

Activity	FY 1986 Appropriation	Sequestration	FY 1986 available after Sequestering
Block Grants	$335,000,000	$-14,405,000	$320,595,000
Discretionary Activities	31,000,000	-1,333,000	29,667,000
Economic Development	18,350,000	-789,000	17,561,000
Rural Hsg. & Facilities	3,720,000	-160,000	3,560,000
Migrants	2,800,000	-120,000	2,680,000
Nat'l Youth Sports Prog.	6,130,000	-264,000	5,866,000
Federal Administration	4,300,000	-185,000	4,115,000
Totals	$370,300,000	$-15,923,000	$354,377,000

Effect of Sequestration

Block Grants: The attached table shows Community Services Block Grant (CSBG) allotments available to States and Outlying Areas under the FY 1986 Appropriation; available after sequestering; and the dollar impact of the across-the-board 4.3% sequester reduction.

Discretionary Activities: The 4.3% sequester reduction of $1,333,000 would reduce the number of projects funded in FY 1986 to approximately 65-70 as compared to a total of 77 projects funded in FY 1985.

Federal Administration: The sequester reduction of $185,000 will be absorbed through management efficiencies and savings in areas of travel, printing and reproduction, supplies, equipment and other overhead expenses.

Allocations to States for Community Services Block Grants

Effect of Sequestration

State or Outlying Area	1986 Appropriation	1986 Available after Sequestering	Sequester Reduction
TOTAL	$335,000,000	$320,595,000	$-14,405,000
Alabama	6,384,563	6,110,027	-274,536
Alaska	801,324	766,867	-34,457
American Samoa	218,593	209,194	-9,399
Arizona	2,832,390	2,710,597	-121,793
Arkansas	4,735,054	4,531,447	-203,607
California	31,058,799	29,723,271	-1,335,528
Colorado	3,029,646	2,899,371	-130,275
Connecticut	4,202,730	4,022,013	-180,717
Delaware	915,000	875,655	-39,345
Dist. of Columbia	5,720,839	5,474,843	-245,996
Florida	10,124,012	9,688,679	-435,333
Georgia	9,368,243	8,965,409	-402,834
Guam	206,881	197,985	-8,896
Hawaii	1,455,676	1,393,082	-62,594
Idaho	897,595	858,998	-38,597
Illinois	16,452,752	15,745,284	-707,468
Indiana	5,070,221	4,852,201	-218,020
Iowa	3,768,985	3,606,919	-162,066
Kansas	2,842,347	2,720,126	-122,221
Kentucky	5,871,993	5,619,497	-252,496
Louisiana	8,178,729	7,827,044	-351,685
Maine	1,828,634	1,750,003	-78,631
Maryland	4,777,771	4,572,327	-205,444
Massachusetts	8,681,480	8,308,176	-373,304
Michigan	12,900,905	12,346,166	-554,739
Minnesota	4,192,872	4,012,579	-180,293
Mississippi	5,528,766	5,291,029	-237,737
Missouri	9,637,691	9,223,270	-414,421
Montana	1,149,161	1,099,747	-49,414
Nebraska	2,425,777	2,321,469	-104,308
Nevada	911,842	872,633	-39,209
New Hampshire	943,068	902,516	-40,552
New Jersey	9,542,399	9,132,076	-410,323
New Mexico	1,924,511	1,841,757	-82,754
New York	30,223,908	28,924,280	-1,299,628

Allocations to States for
Community Services Block Grants (Continued)

Effect of Sequestration

State or Outlying Area	1986 Appropriation	1986 Available after Sequestering	Sequester Reduction
North Carolina	$ 9,112,974	$ 8,721,116	$ -391,858
North Dakota	857,551	820,676	-36,875
No. Mariana Islands	129,601	124,028	-5,573
Ohio	13,577,545	12,993,710	-583,835
Oklahoma	4,365,413	4,177,700	-187,713
Oregon	2,789,772	2,669,812	-119,960
Pennsylvania	14,747,344	14,113,208	-634,136
Puerto Rico	14,671,767	14,040,881	-630,886
Rhode Island	1,924,530	1,841,775	-82,755
South Carolina	5,351,888	5,121,757	-230,131
South Dakota	926,928	887,070	-39,858
Tennessee	6,864,350	6,569,183	-295,167
Texas	16,771,489	16,050,315	-721,174
Trust Terr. Pacific Islands	989,152	946,618	-42,534
Utah	1,324,492	1,267,539	-56,953
Vermont	975,927	933,962	-41,965
Virgin Islands	285,773	273,485	-12,288
Virginia	5,576,257	5,336,478	-239,779
Washington	4,118,502	3,941,406	-177,096
West Virginia	3,897,137	3,729,560	-167,577
Wisconsin	4,236,587	4,054,414	-182,173
Wyoming	915,000	875,655	-39,345
Indian Tribes Set Aside	1,784,864	1,708,115	-76,749

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEPARTMENTAL MANAGEMENT

General Departmental Management

Effect of Sequestration

	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestration [1]
General Departmental Management (GDM):			
Direct Program..............	[illegible]	[illegible]	$114,419,000
AIDS [illegible]..............	[illegible]	-688,000	15,312,000
[illegible]..............	[illegible]	[illegible]	4,487,000
Subtotal, [illegible]	[illegible]	[illegible]	[illegible]
Trust Fund Transfer..........	[illegible]	[illegible]	[illegible]
Total [illegible]..........	[illegible]	[illegible]	[illegible]

[illegible]

Direct Program

The 4.3 percent sequestration will [illegible] performed under General Departmental Management [illegible] Office of the Secretary. [illegible]

[illegible]

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[1] [illegible]

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Special efforts will be made to minimize adverse effect on the major Departmental administrative systems operated under [illegible], including the Department's Payment Management System which pays recipients of HHS program grants, and the Department's payroll system which pays approximately 100,000 Departmental employees every two weeks.

AIDS demonstrations:

The 4.3 percent sequestration reduction would decrease the amount of the demonstration projects by $688,000. A reduction of this amount should not necessitate a decrease in the number of awards made, but only in the size of the awards.

Cancer construction:

The 4.3 percent reduction would decrease by $[illegible] the amount transferred from the National Cancer Institute and available for new construction of the Mary Babb Randolph Cancer Center in West Virginia.

Cancer construction:

The 4.3 percent reduction would decrease by $[illegible] the amount transferred from the National Cancer Institute and available for new construction of the Mary Babb Randolph Cancer Center in West Virginia.

Trust fund transfer:

Reimbursement from the Social Security Act trust funds would be decreased by $[illegible] under the 4.3 percent sequestration. The effect of this decrease is described within the description above for "[illegible]."

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEPARTMENTAL MANAGEMENT

Office for Civil Rights

Effect of Sequestration

	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestration
Salaries and expenses:			
Budget Authority........	[illegible]	[illegible]	[illegible]
Trust fund transfers....	[illegible]	[illegible]	[illegible]
Total, BA..........	[illegible]	[illegible]	[illegible]

Effect of Sequestration

[illegible]

[illegible]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEPARTMENTAL MANAGEMENT

Office of Inspector General

Effect of Sequestration

	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestration
Office of Inspector General (OIG):			
Direct program......	$42,219,000	-$1,815,000	$40,404,000
Trust fund transfer.	31,000,000	- 1,290,000	29,710,000
Total, OIG........	$73,219,000	- 3,105,000	$70,114,000

Effect of Sequestration

Direct program:

The 4.3 percent sequestration should have minor effects on the OIG productivity in FY 1986. With increased management oversight, the OIG will maintain, or possibly increase, the 1985 level of productivity. (This is due, in part, to the elapsed time between initiating audits, inspections and investigations and the final action leading to statistical results.)

Dollar reductions are resulting in:

1. Staff reductions of 37 FTEs
2. Reduced audits and inspections done by contract
3. Deferred purchase of software equipment
4. Deferred staff promotions

Dollar reductions are not expected to require imposition of employee furloughs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEPARTMENTAL MANAGEMENT

Policy Research

Effect of Sequestration

	FY 1986 Appropriation	Sequestration	FY 1986 Available (Post Sequestration)
Policy Research......	[illegible]	[illegible]	[illegible]

Effect of Sequestration:

Sequestration will reduce by [illegible] amounts otherwise available for new and continuing projects. The reduction will be made by (1) reducing funding for the lowest priority activities, and (2) reducing the scope of the remaining projects.

DEPARTMENTAL MANAGEMENT

Office of Consumer Affairs

Effect of Sequestration

	FY 1986 Appropriation	Sequestration	FY 1986 Available After Sequestering
Office of Consumer Affairs............	$1,988,000	-$85,000	$1,903,000

Effect of Sequestration

The Office of Consumer Affairs will accomplish the 1986 sequestration through a reduction in staff work years and associated expenses. In order to begin FY 1987 at the request level, a staff reduction from 11 employees to 5 was projected for the end of FY 1986. This staff reduction will be moved forward in order to realize the savings required under this sequester order.

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Department of Health and Human Services
National Support for Performance of Medical and Health-Related R&D,
by Source of Funds, 1979-1985[1]

(Millions of Dollars)

Source of Funds	1979	1980	1981	1982	1983	1984 est.	1985 est.
Total	$7,113	$7,914	$8,540	$9,239	$10,208	$11,533	$12,823
Government	4,721	5,145	5,340	5,527	5,971	6,684	7,473
Federal	4,321	4,723	4,848	4,970	5,399	6,082	6,847
NIH	2,953	3,182	3,333	3,433	3,789	4,252	4,824
State & local	400	422	492	557	572	602	626
Industry[2]	2,093	2,456	2,875	3,373	3,887	4,486	4,973
Private nonprofit	299	313	325	339	350	363	377
Foundations	60	54	52	44	41	38	36
Vol. health agencies	131	148	160	177	186	196	206
Other	108	111	113	118	123	129	135

[1] Excludes research training and construction. Includes U.S.-funded health R&D support spent abroad. Updated 1984-1985 and estimated 1986 figures will be available in Summer 1986.

[2] Revised 1985.

Note: Federal data are obtained via an interagency survey conducted by the National Institutes of Health. Estimates for State and local governments include awards made by governmental agencies, as well as appropriations made to educational institutions for the performance of health R&D. The industry sector includes data for the pharmaceutical, medical supply, and biomedical engineering industries. The non-industrial private sector covers the funds provided by philanthropic foundations, voluntary health agencies, and other private contributors for the support of health R&D.

Department of Health and Human Services
Federal Obligations for Support of Medical and Health-Related R&D, by Source of Funds
Fiscal Years 1979-1985[1]

(Millions of Dollars)

Source of Funds	1979	1980	1981	1982	1983	1984 est.	1985 est.
Total, all agencies	$4,321.2	$4,722.6	$4,848.4	$4,970.2	$5,399.3	$6,081.9	$6,847.3
HHS, total (HEW)	3,450.7	3,694.0	3,826.8	3,890.7	4,317.0	4,795.1	5,404.9
Nat'l Institutes of Health	2,953.1	3,181.8	3,333.2	3,433.1	3,789.2	4,251.6	4,824.4
Other Public Health Service	419.9	458.0	444.1	422.4	484.4	499.7	539.8
Other HHS (HEW)	77.6	54.1	49.5	35.1	43.3	43.8	40.7
Other agencies, total	870.5	1,028.6	1,021.6	1,079.5	1,082.3	1,286.8	1,442.4
Department of Agriculture	112.4	147.3	149.5	161.9	147.2	147.9	147.7
Department of Defense	186.4	211.0	242.9	279.7	307.4	414.2	475.7
Department of Education	na	32.1	30.8	29.8	29.3	41.0	44.0
Department of Energy (ERDA)	191.8	210.9	188.0	197.0	168.5	182.7	191.3
Environmental Protection Agency	67.2	78.1	74.5	48.7	39.9	43.5	55.6
Int'l Dev. Coop. Agency (AID)	20.2	13.4	11.4	25.8	31.1	17.7	36.1
Nat'l Aeronautics & Space Adm.	41.4	71.8	67.7	79.0	76.0	110.2	115.0
National Science Foundation	73.8	75.7	67.2	75.3	77.0	86.8	97.0
Veterans Administration	127.0	133.4	144.4	137.3	161.4	190.3	226.4
All other dept's & agencies	50.3	54.9	45.2	45.1	44.5	52.4	53.6

[1] Excludes research training and construction. Includes U.S.-funded health R&D support spent abroad. Totals may not add because of rounding. Updated 1984-1985 and estimated 1986 figures will be available in Summer 1986.

Note: Federal data are obtained via an interagency survey conducted by the National Institutes of Health.

NATIONAL HEALTH EXPENDITURES: Private Expenditures and Expenditures Under Public Programs, Selected Calendar Years 1929-1984 (Amounts in Millions)

Type of Expenditure	1929	1950	1955	1960
Total	$3,649	$12,662	$17,747	$26,895
Private Expenditures	3,154	9,222	13,190	20,259
Health Services and Supplies	3,049	8,895	12,889	19,598
Direct (out-of-pocket) Expenses	n/a	7,142	9,132	12,990
Insurance Benefits	n/a	992	2,536	4,996
Net Cost of Health Insurance	108	350	614	845
Other 1/	112	460	627	767
Noncommercial Medical Research	—	38	62	125
Construction of Medical Facilities	105	299	241	536
Public Expenditures	495	3,440	4,555	6,637
Health Services and Supplies	387	2,817	3,995	5,587
Medicare (Title XVIII)	—	—	—	—
Medicaid (Title XIX)	—	—	—	—
Temporary Disability Insurance 2/	—	7	21	41
Workers Compensation 2/	[illegible]	204	325	435
Public Assistance (Medical Payments) Other Than Medicaid	—	76	232	514
Defense Department Hospital and Medical Care (Including Military Dependents)	29	594	754	606
Maternal and Child Health	6	32	98	148
School Health (Educational Agencies)	10	31	65	108
Veterans' Hospital and Medical Care	49	582	721	911
Medical Vocational Rehabilitation	[illegible]	8	10	18
OEO Health and Medical Care	—	—	—	—
Hospital and Medical Care n.e.c.	120	911	1,184	2,100
Public Health Activity	36	361	377	414
Medical Research	—	70	150	508
Construction of Medical Facilities	108	344	419	512
National Health Expenditures as a Percent of Gross National Product	3.5%	4.5%	4.4%	5.3%
Public Expenditures as a Percent of Total Expenditures	13.6%	27.2%	25.7%	24.7%
Personal Health Care Expenditures 4/	$3,202	$10,885	$15,708	$23,680
Private Expenditures	2,913	8,445	12,050	18,523
Public Expenditures	289	2,440	3,658	5,157
Percent Distribution of Personal Health Care Expenditures, by Source of Funds	100.0%	100.0%	100.0%	100.0%
Private Payments	91.0	77.6	77.0	78.2
Consumer Direct Payments	n/a	68.5	58.1	54.9
Insurance Benefits	n/a	9.1	18.9	23.3
Public Payments	9.0	22.4	23.0	21.8

Source: Office of the Actuary, Health Care Financing Administration

1/ Industrial in-plant services and philanthropy.

2/ Includes medical benefits paid under public law by private carriers and by self-insures.

3/ Included with "hospital and medical care n.e.c."

4/ Differs from "health and medical services" by the exclusion of (1) "expenses for prepayment," (2) administration, (3) public health activities.

NATIONAL HEALTH EXPENDITURES: Private Expenditures and Expenditures Under Public Programs, H-2
Selected Calendar Years 1929-1984
(Amounts in Millions)

Type of Expenditure	1965	1970	1975	1976
Total	$41,929	$74,999	$132,680	$150,760
Private Expenditures	31,341	47,227	76,306	87,970
Health Services and Supplies	29,477	44,442	72,520	84,457
Direct (Out-of-pocket) Expenses	18,511	26,498	38,081	42,221
Insurance Benefits	8,145	15,328	31,278	37,580
Net Cost of Health Insurance	1,137	1,551	1,907	2,809
Other 1/	961	1,233	1,351	2,550
Non-commercial Medical Research	178	215	208	267
Construction of Medical Facilities	1,292	2,385	3,572	3,245
Public Expenditures	10,588	27,772	56,374	62,790
Health Services and Supplies	9,588	24,913	51,258	57,284
Medicare (Title XVIII)	–	7,498	16,377	19,300
Medicaid (Title XIX)	–	5,471	14,155	15,616
Temporary Disability Insurance 2/	42	56	75	71
Workers' Compensation 2/	798	1,409	2,432	2,758
Public Assistance (Medical Payments) Other Than Medicaid	2,112	858	945	1,016
Defense Department Hospital and Medical Care (Including Military Dependents)	801	1,782	2,430	2,564
Maternal and Child Health	256	429	594	643
School Health (Educational Agencies)	170	240	361	377
Veterans' Hospital and Medical Care	1,115	1,784	3,415	4,152
Medical Vocational Rehabilitation	47	119	177	184
OEO Health and Medical Care	22	170	3/	3/
Hospital and Medical Care N.E.C.	2,999	3,769	4,750	6,180
Public Health Activity	815	1,410	3,157	3,884
Medical Research	1,389	1,754	3,073	3,438
Construction of Medical Facilities	354	1,086	1,848	2,068
National Health Expenditures as a Percent of Gross National Product	6.1%	7.5%	8.6%	8.8%
Public Expenditures as a Percent of Total Expenditures	25.2%	37.0%	42.5%	41.6%
Personal Health Care Expenditures 4/	$35,650	$65,249	$117,173	$132,804
Private Expenditures	27,695	42,808	70,893	81,415
Public Expenditures	7,955	22,441	46,280	51,389
Percent Distribution of Personal Health Care Expenditures, by Source of Funds	100.0%	100.0%	100.0%	100.0%
Private Payments	77.5	65.7	60.5	61.3
Consumer Direct Payments	51.6	40.5	32.5	31.6
Insurance Benefits	24.2	23.4	26.9	28.2
Public Payments	22.5	34.3	39.5	38.7

Source: Office of the Actuary, Health Care Financing Administration

1/ Industrial in-plant services and philanthropy.
2/ Includes medical benefits paid under public law by private carriers and by self-insurers.
3/ Included with "hospital and medical care n.e.c."
4/ Differs from "health and medical services" by the exclusion of (1) "expenses for prepayment," (2) administration, (3) public health activities.

NATIONAL HEALTH EXPENDITURES: Private Expenditures and Expenditures Under Public Programs, Selected Calendar Years 1929-1984 (Amounts in Millions) H-2

Type of Expenditure	1977	1978	1979	1980
Total	$169,855	$189,657	$214,659	$247,516
Private Expenditures	100,117	110,091	124,182	142,170
Health Services and Supplies	96,651	106,558	120,423	137,888
Direct (out-of-pocket) Expenses	46,448	50,670	55,825	62,477
Insurance Benefits	42,962	49,084	56,914	67,288
Net Cost of Health Insurance	5,054	4,493	5,098	5,180
Other 1/	2,187	2,312	2,586	2,944
Non-commerical Medical Research	273	282	299	313
Construction of Medical Facilities	3,193	3,250	3,460	3,967
Public Expenditures	69,738	79,567	90,477	105,347
Health Services and Supplies	64,036	73,136	83,806	97,704
Medicare (Title XVIII)	22,525	25,932	30,337	36,813
Medicaid (Title XIX)	17,721	19,812	22,867	26,466
Temporary Disability Insurance 2/	74	80	58	52
Workers Compensation 2/	3,191	3,682	4,541	5,151
Public Assistance (Medical Payments) Other Than Medicaid	1,137	1,307	1,473	1,645
Defense Department Hospital and Medical Care (Including Military Dependents)	3,062	3,442	3,779	4,207
Maternal and Child Health	692	731	806	892
School Health (Educational Agencies)	432	495	532	589
Veterans' Hospital and Medical Care	4,400	4,984	5,313	5,941
Medical Vocational Rehabilitation	201	211	224	216
OEO Health and Medical Care	3/	3/	3/	3/
Hospital and Medical Care N.E.C.	6,601	7,670	7,936	8,516
Public Health Activity	4,001	4,990	5,941	7,216
Medical Research	3,631	4,137	4,416	5,110
Construction of Medical Facilities	2,071	2,093	2,255	2,532
National Health Expenditures as a Percent of Gross National Product	8.9%	8.8%	8.9%	9.4%
Public Expenditures as a Percent of Total Expenditures	41.1%	42.0%	42.1%	42.6%
Personal Health Care Expenditures 4/	$149,145	$167,365	$189,662	$219,138
Private Expenditures	91,364	101,838	115,064	132,404
Public Expenditures	57,781	65,528	74,597	86,734
Percent Distribution of Personal Health Care Expenditures, by Source of Funds	100.0%	100.0%	100.0%	100.0%
Private Payments	61.3	60.8	60.7	60.4
Consumer Direct Payments	31.1	30.3	29.4	28.5
Insurance Benefits	28.6	29.3	30.0	30.7
Public Payments	38.7	39.2	39.3	39.6

Source: Office of the Actuary, Health Care Financing Administration

1/ Industrial in-plant services and philanthropy.
2/ Includes medical benefits paid under public law by private carriers and by self-insures.
3/ Included with "hospital and medical care n.e.c."
4/ Differs from "health and medical services" by the exclusion of (1) "expenses for prepayment," (2) administration, (3) public health activities.

NATIONAL HEALTH EXPENDITURES: Private Expenditures and Expenditures Under Public Programs, H-2
Selected Calendar Years 1929-1984
(Amounts in Millions)

Type of Expenditure	1981	1982	1983	1984
TOTAL	$286,[illegible]	$322,[illegible]	$355,[illegible]	$390,151
Private Expenditures	164,172	186,111	207,[illegible]	227,[illegible]
Health Services and Supplies	159,[illegible]	178,[illegible]	200,[illegible]	220,[illegible]
Direct (Out-of-pocket) Payments	75,794	75,142	86,179	95,366
Insurance Premiums	70,704	90,717	100,281	107,151
Net Cost of Health Insurance	[illegible]	[illegible]	[illegible]	11,399
Other 1/	3,4[illegible]	3,872	4,[illegible]	4,424
Non-commercial Medical Research	[illegible]	300	318	3[illegible]
Construction of Medical Facilities	[illegible]	[illegible]	6,454	6,363
Public Expenditures	[illegible]	[illegible]	[illegible]	[illegible]
Health Services and Supplies	[illegible]	[illegible]	[illegible]	[illegible]
Medicare (Title XVIII)	44,741	52,[illegible]	58,[illegible]	64,[illegible]
Medicaid (Title XIX)	[illegible]	[illegible]	[illegible]	38,[illegible]
Temporary Disability Insurance 2/	52	55	54	55
Workers' Compensation	[illegible]	[illegible]	[illegible]	7,[illegible]
Public Assistance (Medical Vendor Payments Other Than Medicaid)	[illegible]	[illegible]	[illegible]	[illegible]
Defense Department Hospital and Medical Care (including Military Dependents)	[illegible]	[illegible]	[illegible]	[illegible]
Maternal and Child Health	[illegible]	[illegible]	[illegible]	[illegible]
School Health (Educational Agencies)	[illegible]	[illegible]	[illegible]	[illegible]
Veterans' Hospital and Medical Care	[illegible]	[illegible]	[illegible]	[illegible]
Medical Vocational Rehabilitation	[illegible]	[illegible]	[illegible]	[illegible]
[illegible] and Medical Care	3/	3/	3/	3/
Hospital and Medical Care N.E.C.	[illegible]	[illegible]	[illegible]	[illegible]
Public Health Activity	[illegible]	[illegible]	[illegible]	[illegible]
Medical Research	[illegible]	[illegible]	[illegible]	[illegible]
Construction of Medical Facilities	[illegible]	[illegible]	[illegible]	2,[illegible]
National Health Expenditures as a Percent of Gross National Product	[illegible]	[illegible]	[illegible]	10.[illegible]
Public Expenditures as a Percent of Total Expenditures	42.[illegible]	42.1%	41.[illegible]	41.[illegible]
Personal Health Care Expenditures 4/	[illegible]	[illegible]	[illegible]	[illegible]
Private Expenditures	[illegible]	[illegible]	[illegible]	[illegible]
Public Expenditures	[illegible]	[illegible]	[illegible]	[illegible]
Percent Distribution of Personal Health Care Expenditures, by Source of Funds	100.0%	100.0%	100.0%	100.0%
Private Payments	60.2	60.2	60.4	60.4
Consumer Direct Payments	[illegible]	[illegible]	[illegible]	[illegible]
Insurance Benefits	[illegible]	[illegible]	[illegible]	[illegible]
Public Payments	39.8	39.8	39.6	39.6

Source: Office of the Actuary, Health Care Financing Administration.

1/ Industrial in-plant services and philanthropy.
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3/ Included with "Hospital and medical care n.e.c."
4/ Differs from "Health and medical services" by the exclusion of (1) "expenses for prepayment," (2) administration, (3) public health activities.

Department of Health and Human Services

NATIONAL INSTITUTES OF HEALTH

Year End Status of Extramural Programs

RESEARCH PROJECT GRANTS

(Amount in thousands)

H-3 (1)

	1985		1986 APPROPRIATION		1986 APPROPRIATION AFTER SEQUESTRATION		1986 REVISED		1987 REQUEST	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount
NCI:										
Funded	[illegible]	$516,[illegible]	3082	$569,243	3082	$563,970	3008	$557,170	2924	$517,134
Unfunded	[illegible]	[illegible]	2160	355,139	2160	362,534	2254	369,334	2193	445,998
NHLBI:										
Funded	2638	475,[illegible]	2708	515,734	2708	510,811	2639	499,342	2605	498,906
Unfunded	1587	[illegible]	1637	229,139	1637	236,694	1706	246,163	1803	304,994
NIDR:										
Funded	[illegible]	47,[illegible]	393	47,040	393	44,991	397	44,991	379	43,244
Unfunded	[illegible]	[illegible]	199	26,541	199	27,277	199	27,277	242	36,327
NIADDK:										
Funded	2031	298,815	2044	319,941	2044	306,297	1931	299,881	1927	291,143
Unfunded	467	133,279	1184	145,016	1184	147,947	1257	154,803	1329	180,881
NINCDS:										
Funded	1858	257,518	1919	298,203	1919	281,619	1871	272,065	1851	269,735
Unfunded	1581	169,751	1592	230,514	1592	237,036	1649	246,590	1854	310,264
NIAID:										
Funded	1717	245,096	1724	257,323	1724	246,282	1662	244,769	1599	229,943
Unfunded	994	130,174	1089	134,512	1089	147,026	1151	145,930	1155	158,791
NIGMS:										
Funded	2904	396,837	2945	429,895	2945	411,268	2781	403,910	2721	394,079
Unfunded	1214	138,852	1363	142,823	1363	167,341	1525	175,856	1557	201,459
NICHD:										
Funded	1367	187,634	1374	199,281	1374	190,665	1358	189,515	1369	189,631
Unfunded	1193	136,238	1281	157,592	1281	160,396	1297	160,796	1395	185,336
NEI:										
Funded	1118	137,[illegible]	1141	149,415	1141	142,994	1114	137,770	1103	137,261
Unfunded	377	46,857	299	38,781	299	40,897	326	43,993	449	64,651
NIEHS:										
Funded	282	52,632	358	56,632	358	54,197	358	54,197	334	52,913
Unfunded	226	28,789	252	32,810	252	33,538	252	33,538	312	45,554
NIA:										
Funded	478	81,671	504	92,700	504	88,771	480	86,092	490	84,248
Unfunded	405	56,409	381	58,002	381	59,149	405	67,019	434	73,530
NIAMSD:										
Funded	565	77,554	582	83,599	582	80,030	556	78,506	537	75,011
Unfunded	371	43,156	429	55,923	429	57,070	455	58,594	506	71,002
TOTAL:										
Funded	18357	2,765,899	18776	3,052,677	18776	2,921,895	18195	2,868,168	17889	2,803,248
Unfunded	10464	1,308,746	11886	1,631,751	11886	1,672,802	12467	1,726,493	13506	2,078,787

Department of Health and Human Services

NATIONAL INSTITUTES OF HEALTH

Year-End Status of Extramural Programs
Training Programs

INDIVIDUAL AWARDS

(Amount in thousands)

	1985		1986 APPROPRIATION		1986 REVISED 1/		1987 REQUEST	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
NCI:								
Funded	[illegible]	$5,753	185	$4,626	185	$5,522	187	$4,292
Unfunded	[illegible]	[illegible]	[illegible]	[illegible]	121	7,446	177	4,596
NHLBI:								
Funded	260	[illegible]	234	[illegible]	227	[illegible]	203	5,140
Unfunded	94	[illegible]	58	1,441	73	1,942	82	2,076
NIDR:								
Funded	37	914	54	1,558	48	1,498	42	1,350
Unfunded	[illegible]	[illegible]	5	[illegible]	5	125	5	125
NIADDK:								
Funded	[illegible]	4,271	121	2,965	120	2,957	118	2,858
Unfunded	88	2,990	151	3,747	152	3,275	163	4,044
NINCDS:								
Funded	[illegible]	5,866	209	4,541	199	4,160	199	4,307
Unfunded	[illegible]	1,715	170	5,740	180	1,118	174	3,629
NIAID:								
Funded	[illegible]	1,848	61	2,658	69	1,721	55	1,418
Unfunded	152	1,297	150	4,144	175	4,498	193	4,895
NIGMS:								
Funded	[illegible]	10,614	385	7,678	312	6,831	194	4,488
Unfunded	[illegible]	8,774	529	11,476	562	12,105	658	16,279
NICHD:								
Funded	141	2,924	103	2,550	99	2,440	95	2,351
Unfunded	104	2,261	137	3,251	141	3,761	180	3,840
NEI:								
Funded	111	2,465	108	2,615	108	2,503	98	2,388
Unfunded	[illegible]	550	53	1,924	53	1,964	64	1,357
NIEHS:								
Funded	44	734	36	710	36	679	33	670
Unfunded	5	200	5	100	5	100	6	120
NIA:								
Funded	24	551	33	782	32	748	30	713
Unfunded	13	396	15	277	16	311	20	392
NIAMS:								
Funded	32	741	37	920	35	881	35	881
Unfunded	18	550	22	543	24	507	27	678
FIC:								
Funded	4	91	3	84	3	81	3	84
Unfunded	--	---	1	28	1	28	2	56
TOTAL:								
Funded	1831	41,267	1569	36,888	1473	34,544	1292	30,630
Unfunded	1074	21,330	1411	31,979	1508	34,567	1741	42,087

1/ The 1986 Appropriation after sequestration is the same as the 1986 Revised.

Department of Health and Human Services

NATIONAL INSTITUTES OF HEALTH

H-I (1)

Year-End Status of Extramural Programs
Training Programs

INSTITUTIONAL AWARDS

(Amount in thousands)

	1985		1986 APPROPRIATION		1986 REVISED 1/		1987 REQUEST	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
NCI:								
Funded	142	$25,499	185	$26,217	116	$25,085	128	$24,318
Unfunded	17	1,765	345	14,467	354	15,574	59	7,584
NHLBI:								
Funded	261	34,432	255	38,175	255	32,705	221	28,629
Unfunded	11	971	25	2,616	25	4,096	54	5,363
NIDR:								
Funded	47	3,829	49	3,312	45	3,170	45	3,312
Unfunded	5	446	5	411	9	960	4	484
NIADDK:								
Funded	54	16,324	32	17,615	23	16,757	19	16,186
Unfunded	29	2,291	45	5,183	54	5,907	61	6,718
NINCDS:								
Funded	32	7,554	11	8,452	7	8,280	17	8,280
Unfunded	17	1,366	21	1,535	25	1,907	27	2,078
NIAID:								
Funded	38	9,538	8	9,226	7	9,171	8	7,569
Unfunded	20	1,381	25	2,053	27	2,460	29	2,732
NIGMS:								
Funded	264	47,255	268	50,045	252	48,408	201	48,432
Unfunded	34	6,877	17	7,307	25	8,947	70	15,445
NICHD:								
Funded	100	10,958	95	11,351	91	10,863	88	10,749
Unfunded	18	1,556	26	3,129	30	3,688	39	4,680
NEI:								
Funded	9	2,356	3	2,816	3	2,504	2	2,388
Unfunded	8	1,035	7	1,065	7	1,282	8	1,382
NIEHS:								
Funded	47	7,216	42	7,242	42	7,451	38	7,336
Unfunded	7	778	5	990	5	1,325	8	1,221
NIA:								
Funded	10	4,058	7	4,725	5	4,522	7	4,396
Unfunded	3	248	7	771	9	1,145	8	1,029
NIAMSD:								
Funded	18	5,387	5	5,210	3	4,986	8	4,986
Unfunded	7	793	21	2,829	26	2,125	22	1,969
DRR:								
Funded	9	984	9	991	9	948	9	991
Unfunded	6	630	2	480	2	480	2	480
TOTAL:								
Funded	1019	176,290	922	161,920	878	174,856	791	167,574
Unfunded	187	19,849	551	42,099	598	49,621	389	51,163

1/ The 1986 Appropriation after sequestration is the same as the 1986 Revised.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

History of Congressional Action on Budget Requests for National Institutes of Health Institutes and Research Divisions 16/

	Budget Estimate to Congress	Appropriation
1933......	548,000	548,000
1934......	54,775	54,775
1935......	50,000	50,000
1936......	64,000	64,000
1937......	64,000	64,000
1938......	464,000	464,000
1939......	515,000	515,000
1940......	587,750	707,000
1941......	712,120	711,000
1942......	705,000	700,000
1943......	1,278,270	1,278,270
1944......	1,291,000	2,555,020
1945......	2,835,000	2,835,000
1946......	2,078,000	3,414,700
1947......	10,799,500	8,125,448 1/
1948......	22,403,000	28,876,000
1949......	45,701,460	37,668,000
1950......	40,567,000	50,167,000
1951......	49,845,000	47,334,750 3/
1952......	53,386,000	52,447,291
1953......	55,005,000	59,030,750
1954......	56,340,000	71,153,000
1955......	71,128,000	81,268,000
1956 5/6/.	90,023,000	98,458,000
1957......	126,725,000 7/	183,007,000
1958......	190,183,000	211,183,000
1959......	211,814,000	294,383,000
1960......	294,279,000	400,000,000
1961......	400,000,000	560,000,000 8/
1962......	583,000,000	738,335,000 9/
1963......	780,400,000	880,800,000
1964......	930,454,000	918,454,000
1965......	956,492,000	965,992,000
1966 10/	1,105,006,000	1,138,406,000
1967....	1,231,764,000	1,306,983,000
1968 11/	1,152,250,000	1,143,424,000
1969....	1,188,293,000	1,100,092,000
1970....	1,064,570,000 12/	1,122,718,400 13/
1971....	1,099,249,000	1,196,249,000
1972 14/	1,333,916,000	1,476,046,000
1973 15/	1,483,982,000	1,713,455,000
1974....	1,531,776,000	1,744,554,000 17/
1975....	$1,785,922,000	$2,043,721,000
1976 18/	2,349,413,000	2,627,845,000
1977....	2,088,179,000	2,424,510,000
1978....	2,456,104,000	2,720,767,000 19/
1979....	2,794,623,000	3,097,138,000 20/
1980....	3,111,391,000	3,360,670,000
1981....	3,432,146,000	3,490,459,000 21/
1982 22/	3,239,274,000	3,563,324,000 23/
1983....	3,660,945,000	3,929,843,000 23/
1984....	3,980,856,000	4,374,768,000 24/
1985....	4,476,524,000	5,036,344,000
1986....	4,852,680,000	5,501,454,000 25/
1987....	4,936,157,000	

1/ Includes $386,500 transfers.

2/ Not less than $3,000,000 was earmarked for liquidating cash; an additional $1,175,000 was used for that purpose.

3/ Excludes $3,216,250 rescinded.

4/ Excludes $131,000 for Gorgas Memorial Laboratory.

5/ Excludes $147,000 for Gorgas Memorial Laboratory.

6/ Includes $90,000 transfer.

7/ Includes $200,000 transfer from other appropriations.

8/ Includes $12,139,000 for construction of mental health-neurology research facility.

9/ Includes $1,000,000 for planning for a gerontological research facility; and $750,00 for modernization at the Rocky Mountain Laboratory, Hamilton, Montana.

10/ Includes $25,000,000 for Regional Medical Programs, $19,700,000 for Mental Health Staffing, and $20,250,000 for Heart Disease, Cancer and Stroke Program.

11/ Excludes $246,741,000 for National Institute of Mental Health. Includes $20,615,000 for Environmental Health Sciences.

12/ Excludes $7,093,000 for Office of the Director, NIH.

13/ Includes $1,348,200 supplemental.

14/ Includes $142,075,000 supplementals.

15/ Excludes DBS. Request reflects amendment.

16/ Includes only Research Institutes, excludes NLM, B&F, and OD.

17/ House allowance reflects maximum authorized. Reflects P.L. 93-192.

18/ Request reflects amendment requested for 1976 in 1977 budget submission. Estimate and appropriation includes Transition Quarter (15 month period).

19/ Continuing Resolution was Conferees Allowance. Includes supplemental of $17,834,000.

20/ Includes Continuing Resolution for items not considered in P.L. 95-482.

21/ Reflects a rescission of $46,959,000 authorized under P.L. 97-12.

22/ Reflects the September amendment, the original request was $3,680,994,000.

23/ Continuing Resolution.

24/ Includes Continuing Resolution for items not considered in P.L. 98-139.

25/ Reflects transfer of $4,500,000 to DHHS from NCI for the Mary Babb Randolph Cancer Center and an administrative reduction of $3,000,000.

NOTE: Not all amounts on this table are comparable from year to year because of changes in the content of the appropriations.

ALCOHOL, DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION

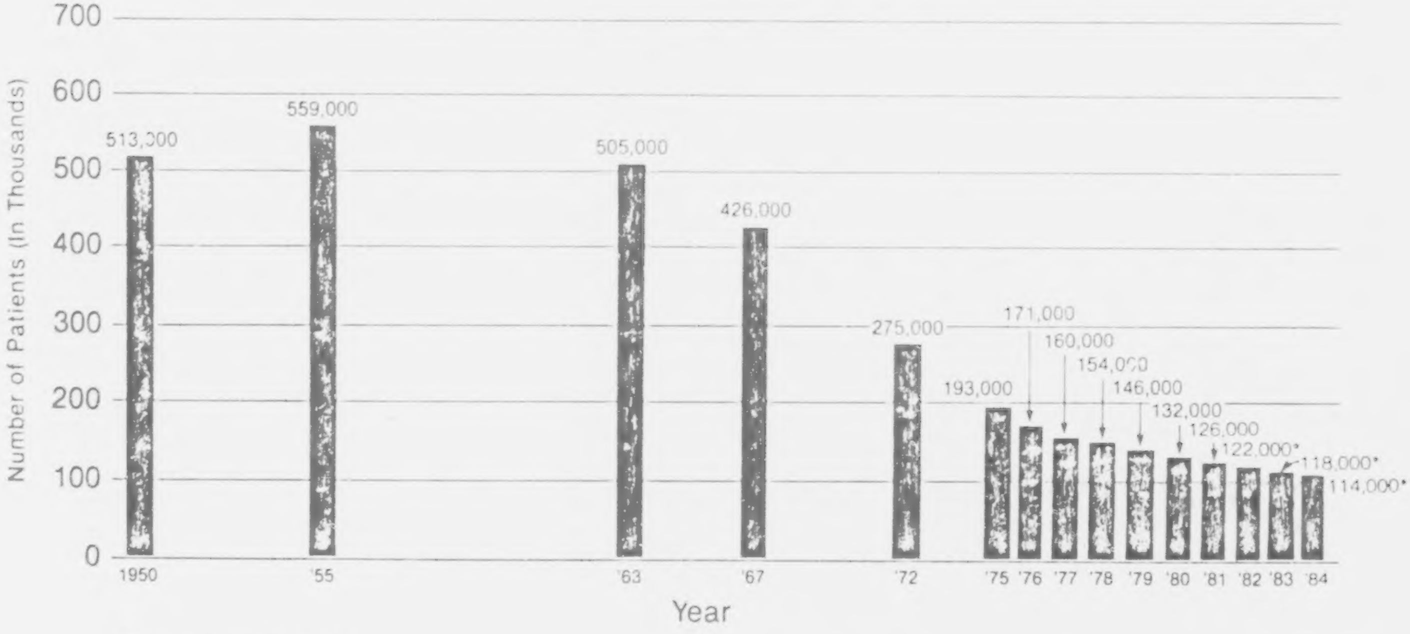
History of Congressional Action on Budget Requests

Year	Budget Estimate Obligation Cash	Appropriation Obligation Cash
1947	$ 4,478,000	$ -0-
1948	5,108,000	4,250,000
1949	11,501,000	9,128,000
1950	9,662,000	10,862,000
1951	7,569,000	7,130,000 1/
1952	10,022,000	9,988,737
1953	10,917,000	10,895,000
1954	9,817,000	12,095,000
1955	12,640,000	14,147,000
1956	17,751,000	18,001,000
1957	21,749,000	35,197,000
1958	35,217,000	39,217,000
1959	37,788,000	52,419,000
1960	52,384,000	68,090,000
1961	67,563,000	100,900,000
1962	88,324,000	108,876,000
1963	176,899,000	143,599,000
1964	190,096,000	183,288,000
1965	224,085,000	222,932,000
1966	278,669,000	282,669,000
1967	305,115,000	315,619,000
1968	346,909,000	346,909,000
1969	364,939,000	350,439,000
1970	357,904,000	360,302,000
1971	346,656,000	389,238,000
1972	500,263,000	613,013,000
1973	603,719,000	803,823,000
1974	645,533,000 2/	815,975,000 3/
1975	692,190,000	795,636,000
1976	653,527,000	813,402,000
T.Q.	129,855,000	117,363,000
1977	645,509,000	885,571,000
1978	881,293,000	941,668,000
1979	1,002,871,000	1,025,085,000
1980	1,115,768,000	1,111,146,000
1981	1,092,724,000	1,024,734,000
1982	821,823,000	860,178,000
1983	372,682,000	885,849,000
1984	420,570,000	915,759,000
1985	471,250,000	923,626,000 4/
1986	928,682,000	968,860,000
1987	892,240,000	

1/ Excludes $495,000 rescinded.
2/ Excludes $636,180,000 for outyear costs not considered by Congress.
3/ Includes $23,114,000 withheld in accordance with Public Law 93-192.
4/ Excludes $1,495,000 withheld in accordance with Section 515 of the Treasury-Postal Service Appropriation Act, 1985.

Actual Number of Resident Patients
End of Year

State and County Mental Hospitals 1950-1984



*Provisional Data

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Paylines for Competing Research Project Grants
Fiscal Years 1977-1987
Data Based on Raw Priority Scores

	(----ACTUAL								----)	(----Estimate		----)
	1977	1978	1979	1980	1981	1982	1983	1984 1/	1985 1/	1986 Approp.2/	1986 Revised	1987
NCI...........	225	230	235	218	197	183	181	184	172	170	160	160
NHLBI..........	234	232	256	206	208	196	195	181	177	190	180	180
NIDR...........	245	255	235	230	225	213	208	210	195	220	220	190
NIDDK..........	219	223	230	221	202	180	184	175	173	170	160	160
NINCDS.........	193	227	240	232	206	189	185	169	157	150	150	140
NIAID..........	181	192	233	204	178	162	166	167	159	160	150	150
NIGMS..........	182	198	227	219	193	175	170	163	165	160	160	150
NICHD..........	203	228	233	200	196	187	179	170	162	170	170	160
NEI............	269	272	262	232	212	203	201	193	198	210	200	170
NIEHS..........	255	239	238	217	247	226	220	224	203	200	200	190
NIA............	291	240	278	227	213	208	190	179	202	210	200	190
NIAMSD.........	--	--	--	--	--	--	--	--	--	170	160	160

1/ NHLBI and NICHD use percentiles for making funding decisions and the priority scores shown are derived from the percentile score listings in an analogous manner.

2/ Paylines reflected for the 1986 Appropriation also apply to the 1986 Appropriation after sequestration.

NOTE: 1) Paylines for actual years represent the 90th percentile priority score based on the number of funded research projects. Paylines for estimated years represent the 100th percentile priority score.

2) 1983-1987 includes the Small Business Innovation Research (SBIR) grants.

3) NIAMSD established in 1986.

NATIONAL INSTITUTES OF HEALTH
RESEARCH PROJECT APPLICATIONS REVIEWED AND FUNDED, FY 1976
(DOLLARS IN THOUSANDS)

INSTITUTE	DIRECT COSTS ONLY						TOTAL COSTS					
	REPORTING YEAR APPLICATIONS				COUNCIL RECOMMENDATION RATE		TOTAL ELIGIBLE FOR FUNDING		FUNDED		AWARD RATE	
	REVIEWED		COUNCIL RECOMMENDED*									
	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT
	10,119	$678,745	7,231	$352,952	71.5	52.0	7,258	$471,518	3,464	$263,002	47.7	55.8
NCI	2,016	181,666	1,358	86,858	67.4	47.8	1,359	113,818	674	68,187	49.6	59.9
NHLBI	1,615	118,485	1,192	61,893	73.8	52.2	1,195	82,139	707	51,123	59.2	62.2
NIDR	348	16,214	180	6,529	51.7	40.3	180	8,801	95	4,904	52.8	55.7
NIADDKD	1,207	74,168	895	41,411	74.2	55.8	895	55,159	447	30,857	49.9	55.9
NINCDS	979	54,582	690	29,000	70.5	53.1	690	39,382	234	17,370	33.9	44.1
NIAID	846	45,073	675	27,901	79.8	61.9	675	37,554	181	14,957	26.8	39.8
NIGMS	1,323	81,320	1,056	45,802	79.8	56.3	1,057	61,509	630	41,116	59.6	66.8
NICHD	1,037	62,595	685	31,418	66.1	50.2	687	41,989	267	19,891	38.9	47.4
NEI	296	15,470	249	10,583	84.1	68.4	249	14,069	161	8,922	64.7	63.4
NIEHS	229	14,015	123	5,518	53.7	39.4	124	8,068	38	3,549	30.6	44.0
NIA	225	15,157	128	6,039	56.9	39.8	147	9,033	30	2,127	20.4	23.5

NOTE: 1) In prior NIH submissions, the total eligible for funding included council recommended for approval plus carryovers for the prior year that were eligible and considered for funding in the subsequent year. A policy decision has recently been made to change the way in which carryover is reported to ensure a greater degree of uniformity in data presentation among the NIH awarding units. As a result of this change, 1) in all years for which actual data is available, the total eligible for funding includes the council recommended for approval plus funded carryover from the prior year; and 2) for the current year and budget year estimates, the total eligible for funding includes only those applications recommended for approval by council.

2) NIA received its first Appropriation in FY 1976. Data for FY 1973, 1974 and 1975 Represent grants funded through the NICHD Appropriation.

NATIONAL INSTITUTES OF HEALTH
RESEARCH PROJECT APPLICATIONS REVIEWED AND FUNDED, FY 1977
(DOLLARS IN THOUSANDS)

INSTITUTE	DIRECT COSTS ONLY						TOTAL COSTS					
	REPORTING YEAR APPLICATIONS				COUNCIL RECOMMENDATION RATE		TOTAL ELIGIBLE FOR FUNDING		FUNDED		AWARD RATE	
	REVIEWED		COUNCIL RECOMMENDED*									
	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT
	13,305	$951,305	9,852	$511,118	74.0	53.7	9,940	$686,848	3,840	$306,897	38.6	44.7
NCI	2,603	228,666	1,740	106,883	66.8	46.7	1,741	141,462	658	65,094	37.8	46.0
NHLBI	2,180	186,485	1,600	98,509	73.4	52.8	1,602	128,400	729	64,797	45.5	50.5
NIDR	414	22,415	230	9,773	55.6	43.6	245	14,050	107	6,795	43.7	48.4
NIADDKD	1,817	118,683	1,431	69,293	78.8	58.4	1,443	93;395	641	45,011	44.4	48.2
NINCDS	1,217	75,350	879	39,519	72.2	52.4	882	53,728	235	17,482	26.6	32.5
NIAID	1,172	65,362	969	41,888	82.7	64.1	971	57,637	268	19,499	27.6	33.8
NIGMS	1,599	105,681	1,356	63,399	84.8	60.0	1,356	84,764	446	34,316	32.9	40.5
NICHD	1,263	82,910	869	43,863	68.8	52.9	873	59,694	290	22,537	33.2	37.8
NEI	459	26,307	393	18,378	85.6	69.9	394	24,585	218	14,351	55.3	58.4
NIEHS	255	18,068	195	10,850	76.5	60.1	210	15,470	116	8,530	55.2	55.1
NIA	326	21,378	190	8,763	58.3	41.0	223	13,661	132	8,485	59.5	62.1

NOTE: In prior NIH submissions, the total eligible for funding included council recommended for approval plus carryovers from the prior year that were eligible and considered for funding in the subsequent year. A policy decision has recently been made to change the way in which carryover is reported to ensure a greater degree of uniformity in data presentation among the NIH awarding units. as a result of this change, 1) in all years for which actual data is available, the total eligible for funding includes the council recommended for approval plus funded carryover from the prior year; and 2) for the current year and budget year estimates, the total eligible for funding includes only those applications recommended for approval by council.

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NATIONAL INSTITUTES OF HEALTH
RESEARCH PROJECT APPLICATIONS REVIEWED AND FUNDED, FY 1978
(DOLLARS IN THOUSANDS)

INSTITUTE	DIRECT COSTS ONLY						TOTAL COSTS					
	REPORTING YEAR APPLICATIONS				COUNCIL RECOMMENDATION RATE		TOTAL ELIGIBLE FOR FUNDING		FUNDED		AWARD RATE	
	REVIEWED		COUNCIL RECOMMENDED*									
	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT
	14,500	$1,034,295	11,249	$589,198	77.6	57.0	11,469	$819,711	5,200	$420,850	45.3	51.3
NCI	2,663	240,245	2,033	126,340	76.3	52.6	2,042	170,644	886	91,035	43.4	53.3
NHLBI	2,129	165,430	1,595	92,045	74.9	55.6	1,625	130,367	759	67,553	46.7	51.8
NIDR	512	30,126	331	16,073	64.6	53.4	365	23,643	144	10,306	39.5	43.6
NIADDKD	2,018	139,323	1,614	79,991	80.0	57.4	1,627	108,961	685	52,241	42.1	47.9
NINCDS	1,271	76,742	995	44,063	78.3	57.4	1,008	61,158	534	35,522	53.0	58.1
NIAID	1,255	76,445	1,086	52,260	86.5	68.4	1,091	71,420	397	31,059	36.4	43.5
NIGMS	1,880	121,492	1,611	77,459	85.7	63.8	1,686	111,461	788	58,232	46.7	52.2
NICHD	1,318	90,600	935	49,216	70.9	54.3	991	70,951	453	34,212	45.7	48.2
NEI	632	40,205	538	26,564	85.1	66.1	542	36,143	350	24,422	64.6	67.6
NIEHS	397	25,820	262	13,535	66.0	52.4	263	18,721	119	9,083	45.2	48.5
NIA	425	27,867	249	11,652	58.6	41.8	249	16,243	85	7,185	34.1	44.2

NOTE: In prior NIH submissions, the total eligible for funding included council recommended for approval plus carryovers from the prior year that were eligible and considered for funding in the subsequent year. A policy decision has recently been made to change the way in which carryover is reported to ensure a greater degree of uniformity in data presentation among the NIH awarding units. As a result of this change, 1) in all years for which actual data is available, the total eligible for funding includes the council recommended for approval plus funded carryover from the prior year; and 2) for the current year and budget year estimates, the total eligible for funding includes only those applications recommended for approval by council.

NATIONAL INSTITUTES OF HEALTH
RESEARCH PROJECT APPLICATIONS REVIEWED AND FUNDED, FY 1979
(DOLLARS IN THOUSANDS)

INSTITUTE	---DIRECT COSTS ONLY---						***TOTAL COSTS***					
	REPORTING YEAR APPLICATIONS				COUNCIL RECOMMENDATION RATE		TOTAL ELIGIBLE FOR FUNDING		FUNDED		AWARD RATE	
	REVIEWED		COUNCIL RECOMMENDED*									
	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT
	14,461	1,132,517	11,207	660,790	77.5	58.3	11,510	924,530	5,944	525,473	51.6	56.8
NCI	2,569	241,099	2,047	141,505	79.7	58.7	2,051	196,288	901	109,549	43.9	55.8
NHLBI	2,239	191,979	1,679	106,179	75.0	55.3	1,699	146,151	942	88,790	55.4	60.8
NIDR	388	23,993	228	10,502	58.8	43.8	288	18,398	131	8,091	45.5	44.0
NIADDKD	1,822	131,682	1,494	80,837	82.0	61.4	1,539	113,440	769	62,975	50.0	55.5
NINCDS	1,236	107,402	921	57,869	74.5	53.9	922	78,584	577	46,232	62.6	58.8
NIAID	1,238	85,136	1,104	59,791	89.2	70.2	1,104	81,467	537	42,951	48.6	52.7
NIGMS	1,860	133,305	1,627	85,561	87.5	64.2	1,754	123,426	1,020	76,219	58.2	61.8
NICHD	1,524	110,323	1,011	58,782	66.3	53.3	1,028	81,898	461	40,918	44.8	50.0
NEI	527	37,449	456	25,749	86.5	68.8	462	36,367	301	25,117	65.2	69.1
NIEHS	327	21,874	220	12,850	67.3	58.7	222	18,131	91	8,907	41.0	49.1
NIA	731	48,275	420	21,165	57.5	43.8	441	30,381	214	15,724	48.5	51.8

NOTE: In prior NIH submissions, the total eligible for funding included council recommended for approval plus carryovers from the prior year that were eligible and considered for funding in the subsequent year. A policy decision has recently been made to change the way in which carryover is reported to ensure a greater degree of uniformity in data presentation among the NIH awarding units. As a result of this change, 1) in all years for which actual data is available, the total eligible for funding includes the council recommended for approval plus funded carryover from the prior year; and 2) for the current year and budget year estimates, the total eligible for funding includes only those applications recommended for approval by council.

NATIONAL INSTITUTES OF HEALTH
RESEARCH PROJECT APPLICATIONS REVIEWED AND FUNDED, FY 1980
(DOLLARS IN THOUSANDS)

INSTITUTE	---------------------	DIRECT COSTS ONLY	---------------------				************	TOTAL COSTS	************			
	REPORTING YEAR APPLICATIONS				COUNCIL RECOMMENDATION		TOTAL ELIGIBLE					
	R E V I E W E D		COUNCIL RECOMMENDED*		RATE		FOR FUNDING		F U N D E D		AWARD RATE	
	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT
	14,142	$1,146,196	11,220	$695,726	79.3	60.7	11,301	$961,547	4,785	$472,484	42.3	49.1
NCI	2,523	244,237	1,975	138,528	78.3	56.7	1,982	192,336	773	92,281	39.0	48.0
NHLBI	2,190	186,739	1,735	114,423	79.2	61.3	1,741	155,449	589	66,478	33.8	42.8
NIDR	329	21,441	216	11,286	65.7	52.6	257	18,863	97	7,600	37.7	40.3
NIADDKD	1,966	146,336	1,628	92,662	82.8	63.3	1,631	126,511	698	61,023	42.8	48.2
NINCDS	1,262	105,855	950	61,232	75.3	57.8	951	82,465	503	51,581	52.9	62.5
NIAID	1,313	97,999	1,179	69,332	89.8	70.7	1,181	96,527	452	39,130	38.3	40.5
NIGMS	1,695	172,334	1,511	85,147	89.1	69.6	1,527	119,166	890	78,563	58.3	65.9
NICHD	1,413	110,481	957	58,948	67.7	53.4	958	81,546	348	32,613	36.3	40.0
NEI	494	36,950	415	24,572	84.0	66.7	416	33,843	217	20,020	52.2	59.2
NIEHS	316	24,142	248	15,038	78.5	62.3	248	21,069	87	8,529	35.1	40.5
NIA	641	49,681	406	24,560	63.3	49.4	409	33,772	131	14,666	32.0	43.4

NOTE: In prior NIH submissions, the total eligible for funding included council recommended for approval plus carryovers from the prior year that were eligible and considered for funding in the subsequent year. A policy decision has recently been made to change the way in which carryover is reported to ensure a greater degree of uniformity in data presentation among the NIH awarding units. As a result of this change, 1) in all years for which actual data is available, the total eligible for funding includes the council recommended for approval plus funded carryover from the prior year; and 2) for the current year and budget year estimates, the total eligible for funding includes only those applications recommended for approval by council.

NATIONAL INSTITUTES OF HEALTH
RESEARCH PROJECT APPLICATIONS REVIEWED AND FUNDED, FY 1981
(DOLLARS IN THOUSANDS)

- A C T U A L -

INSTITUTE	DIRECT COSTS ONLY						TOTAL COSTS					
	REPORTING YEAR APPLICATIONS				COUNCIL RECOMMENDED RATE		TOTAL ELIGIBLE FOR FUNDING		FUNDED		AWARD RATE	
	REVIEWED		COUNCIL RECOMMENDED*									
	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT
	15,731	$1,368,080	12,939	$888,569	82.3	65.0	13,027	$1,240,975	5,109	$545,036	39.2	$43.9
NCI..........	2,731	294,252	2,275	184,761	83.3	62.8	2,276	257,553	814	101,246	35.8	39.3
NHLBI........	2,289	208,042	1,890	135,193	82.6	65.0	1,897	187,137	774	86,484	40.7	46.2
NIDR.........	380	27,565	271	17,103	71.3	62.0	317	27,344	143	13,047	45.1	47.7
NIADDK.......	2,155	176,372	1,840	118,113	85.4	67.0	1,853	163,713	759	74,354	41.0	45.4
NINCDS.......	1,547	130,350	1,198	80,414	77.4	61.7	1,198	110,623	487	51,820	40.6	46.8
NIAID........	1,374	102,528	1,242	76,867	90.4	75.0	1,242	108,959	433	44,713	34.9	41.0
NIGMS........	1,958	160,733	1,769	115,425	90.3	71.8	1,771	160,877	711	74,752	40.1	46.5
NICHD........	1,590	128,413	1,148	76,205	72.2	59.3	1,156	106,876	453	44,897	39.2	42.0
NEI..........	643	50,792	580	37,154	90.2	73.1	580	50,973	304	28,890	52.4	56.7
NIEHS........	300	25,393	229	15,831	76.3	62.3	238	22,632	113	11,568	47.5	51.1
NIA..........	764	63,640	497	31,503	65.1	49.5	499	44,288	118	13,265	23.6	30.0

NOTE: In prior NIH submissions, the total eligible for funding includes council recommended for approval plus carryovers from the prior year that were eligible and considered for funding in the subsequent year. A policy decision has recently been made to change the way in which carryover is reported to ensure a greater degree of uniformity in data presentation among the NIH awarding units. As a result of this change, (1) in all years for which actual data is available, the total eligible for funding includes the council recommended for approval plus funded carryover from the prior year; and (2) for the current year and budget year estimates, the total eligible for funding includes only those applications recommended for approval by council.

NATIONAL INSTITUTES OF HEALTH
RESEARCH PROJECT APPLICATIONS REVIEWED AND FUNDED, FY 1987
(DOLLARS IN THOUSANDS)

- A C T U A L -

INSTITUTE	DIRECT COSTS ONLY						TOTAL COSTS					
	REPORTING YEAR APPLICATIONS				COUNCIL RECOMMENDATION RATE		TOTAL ELIGIBLE FOR FUNDING		F U N D E D		AWARD RATE	
	R E V I E W E D		COUNCIL RECOMMENDED*									
	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT
	16,989	$1,598,512	14,396	$1,081,263	84.7	67.6	14,479	$1,529,076	5,027	$564,620	34.7	$36.9
NCI	2,910	332,809	2,500	217,438	85.9	65.3	2,502	309,509	748	96,775	29.9	31.3
NHLBI	2,455	247,986	2,054	169,529	93.7	68.4	2,055	238,025	765	99,733	37.2	41.9
NIDR	386	29,174	258	16,539	66.8	56.7	275	24,308	108	10,402	39.3	42.8
NIADDK	2,289	203,323	1,985	140,411	86.7	69.1	1,985	193,654	645	68,300	32.5	35.1
NINCDS	1,717	154,044	1,431	100,409	83.3	65.2	1,433	138,639	500	52,921	34.9	38.2
NIAID	1,550	124,526	1,437	96,449	92.7	77.5	1,437	134,865	411	43,918	28.6	32.6
NIGMS	2,330	207,353	2,159	152,895	92.7	73.7	2,206	211,153	859	90,834	38.9	43.0
NICHD	1,599	132,481	1,254	86,736	78.4	65.5	1,254	122,403	439	44,194	35.0	36.1
NEI	643	54,244	561	40,409	87.2	74.5	564	56,592	273	26,910	48.4	47.6
NIEHS	411	37,140	274	20,880	66.7	56.2	274	29,457	104	10,927	38.0	37.1
NIA	699	75,434	483	39,568	69.1	52.5	494	62,899	175	19,706	35.4	31.3

NOTE: In prior NIH submissions, the total eligible for funding includes council recommended for approval plus carryovers from the prior year that were eligible and considered for funding in the subsequent year. A policy decision has recently been made to change the way in which carryover is reported to ensure a greater degree of uniformity in data presentation among the NIH awarding units. As a result of this change, (1) in all years for which actual data is available, the total eligible for funding includes the council recommended for approval plus funded carryover from the prior year; and (2) for the current year and budget year estimates, the total eligible for funding includes only those applications recommended for approval by council.

NATIONAL INSTITUTES OF HEALTH
RESEARCH PROJECT APPLICATIONS REVIEWED AND FUNDED, FY 1983
(DOLLARS IN THOUSANDS)

- A C T U A L -

INSTITUTE	---DIRECT COSTS ONLY---						***TOTAL COSTS***					
	REPORTING YEAR APPLICATIONS				COUNCIL RECOMMENDATION RATE		TOTAL ELIGIBLE FOR FUNDING		FUNDED		AWARD RATE	
	REVIEWED		COUNCIL RECOMMENDED*									
	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT
	16798	$1,618,401	14425	$1,137,912	85.9	$70.3	14482	$1,621,162	5389	$643,396	37.2	$39.7
NCI........	3042	342,512	2606	232,747	85.7	67.9	2610	332,725	886	111,896	33.9	33.6
NHLBI......	2519	266,295	2110	186,143	83.8	69.9	2114	263,259	748	116,989	35.4	44.4
NIDR.......	333	28,134	226	15,791	67.9	56.1	252	24,760	133	13,505	52.8	54.5
NIADDK.....	2210	200,261	1993	148,148	90.2	73.9	2000	209,531	777	87,331	38.9	41.7
NINCDS.....	1785	152,246	1514	104,900	84.8	68.9	1522	150,325	539	53,479	35.4	35.6
NIAID......	1519	140,653	1406	107,278	92.6	76.1	1406	155,515	522	59,910	37.1	38.5
NIGMS......	2188	195,185	2035	148,696	93.0	76.2	2040	209,226	835	92,760	40.9	44.3
NICHD......	1607	135,095	1302	91,524	81.0	67.8	1302	130,069	452	45,852	34.7	35.3
NEI........	597	48,140	549	38,392	91.9	79.8	552	55,466	247	25,930	44.7	46.7
NIEHS......	277	29,962	210	20,615	75.8	68.8	210	29,281	98	14,717	46.7	50.3
NIA........	721	79,918	474	43,678	65.7	54.7	474	61,005	152	21,027	32.1	34.5

NOTE: In prior NIH submissions, the total eligible for funding includes council recommended for approval plus carryovers from the prior yea
that were eligible and considered for funding in the subsequent year. A policy decision has recently been made to change the way in w
carryover is reported to ensure a greater degree of uniformity in data presentation among the NIH awarding units. As a result of this
change, (1) in all years for which actual data is available, the total eligible for funding includes the council recommended for appro
plus funded carryover from the prior year; and (2) for the current year and budget year estimates, the total eligible for funding incl
only those applications recommended for approval by council.

NATIONAL INSTITUTES OF HEALTH
RESEARCH PROJECT APPLICATIONS REVIEWED & FUNDED, 1984 H-7 (9)
(DOLLARS IN THOUSANDS)

-ACTUAL-

	DIRECT COSTS ONLY						TOTAL COSTS					
	REPORTING YEAR APPLICATIONS REVIEWED		COUNCIL RECOMMENDED		COUNCIL RECOMMENDATION RATE		TOTAL ELIGIBLE FOR FUNDING		FUNDED		AWARD RATE	
	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT
NCI	3029	356,334	2,518	232,594	83.1	65.3	2,534	346,450	969	157,635	38.2	45.5
NHLBI	2445	263,877	2,115	183,601	86.5	69.6	2,119	262,700	852	119,808	40.2	45.6
NIDR	372	30,408	283	19,973	76.1	65.5	283	28,786	123	13,438	43.5	46.7
NIADDK	2247	217,378	2,020	160,644	89.9	73.9	2,024	228,882	785	96,542	38.8	42.2
NINCDS	1908	176,279	1,629	127,067	85.4	72.1	1,634	180,337	564	70,907	34.5	39.3
NIAID	1478	137,871	1,378	107,154	93.3	77.7	1,408	156,928	507	61,252	36.0	39.0
NIGMS	2113	198,850	1,953	152,666	92.4	76.8	1,955	217,693	702	89,322	35.9	41.0
NICHD	1661	147,134	1,405	110,221	84.6	73.9	1,472	160,323	415	51,835	29.2	32.3
NEI	660	58,657	613	46,076	92.9	78.6	620	68,288	309	35,387	49.8	51.8
NIEHS	323	32,028	279	24,083	86.4	75.2	280	34,334	138	16,481	49.3	48.0
NIA	645	70,480	459	42,960	71.2	61.0	459	60,691	129	19,309	28.1	31.8
TOTAL,NIH	16,901	1,691,376	14,672	1,207,039	86.8	71.4	14,738	1,745,612	5,493	731,916	37.3	41.9

NOTE: In prior NIH submissions, the total eligible for funding included council recommended for approval plus carryovers from prior year that were eligible and considered for funding in the subsequent year. A policy decision has recently been made to change the way in which carryover is reported to ensure a greater degree of uniformity in data presentation among the NIH awarding units. As a result of this change, 1) in all years for which actual data is available, the total eligible for funding includes the council recommended for approval plus funded carryover from the prior year; and 2) for the current year and budget year estimates, the total eligible for funding includes only those applications recommended for approval by council.

INCLUDES SPIR APPROVED/RECOMMENDED/OR FUNDED

H-7 (10)

NATIONAL INSTITUTES OF HEALTH
RESEARCH PROJECT APPLICATIONS REVIEWED AND FUNDED, 1985
(DOLLARS IN THOUSANDS)

-ACTUAL-

	DIRECT COSTS ONLY						TOTAL COSTS					
	REVIEWED		COUNCIL RECOMMENDED		COUNCIL RECOMMENDATION RATE		TOTAL ELIGIBLE FOR FUNDING		FUNDED		AWARD RATE	
	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT
NCI	3183	$396,209	2788	$289,897	87.6%	73.2%	2791	$423,565	1017	$168,464	36.4%	39.8%
NHLBI	2778	342,953	2441	254,730	87.9	74.3	2448	361,903	901	158,203	36.8	43.7
NIDR	381	33,818	317	25,771	83.2	76.2	318	36,586	131	15,859	41.2	43.3
NIADDK	2462	247,146	2237	186,570	90.9	75.5	2240	267,956	786	104,756	35.1	39.1
NINCDS	2127	261,436	1903	193,758	89.5	74.1	1908	275,725	722	105,978	37.8	38.4
NIAID	1635	159,704	1504	121,960	92	76.4	1504	178,299	549	72,045	36.5	40.4
NIGMS	2299	232,976	2165	184,622	94.2	79.2	2202	268,600	987	133,845	44.8	49.8
NICHD	1880	179,839	1647	137,204	87.6	76.3	1662	200,438	469	64,200	28.2	32
NEI	788	76,202	737	59,914	93.5	78.6	746	87,686	367	47,230	49.2	53.9
NIEHS	389	41,600	334	31,409	85.9	75.5	334	45,373	108	16,624	32.3	36.6
NIA	752	84,258	588	58,176	78.2	69	609	87,304	209	30,895	34.3	35.4
TOTAL, NIH	18674	2,056,141	16661	1,544,011	89.2	75.1	16762	2,233,435	6,246	918,099	37.3	41.1

NOTE: In prior NIH submissions, the total eligible for funding included council recommended for approval plus carryovers from prior year that were eligible and considered for funding in the subsequent year. A policy decision has recently been made to change the way in which carryover is reported to ensure a greater degree of uniformity in data presentation among the NIH awarding units. As a result of this change, 1) in all years for which actual data is available, the total eligible for funding includes the council recommended for approval plus funded carryover from the prior year; and 2) for the current year and budget year estimates, the total eligible for funding includes only those applications recommended for approval by council.

Includes SBIR approved, recommended or funded.

H-7 (11)

NATIONAL INSTITUTES OF HEALTH
RESEARCH PROJECT APPLICATIONS REVIEWED AND FUNDED, 1986
(DOLLARS IN THOUSANDS)

-ESTIMATE-

	DIRECT COSTS ONLY						TOTAL COSTS					
	REVIEWED		COUNCIL RECOMMENDED		COUNCIL RECOMMENDATION RATE		TOTAL ELIGIBLE FOR FUNDING		FUNDED		AWARD RATE	
	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT
NCI	3497	$455,361	3111	$351,616	89.0%	77.2%	3111	$530,846	857	$161,512	27.5%	30.4%
NHLBI	2801	356,762	2523	266,518	90.1	74.7	2523	392,117	817	143,954	32.4	36.7
NIDR	422	41,342	348	30,812	82.5	74.5	348	44,586	149	17,309	42.8	38.8
NIDDK	1921	210,819	1821	167,123	94.8	79.3	1821	241,159	564	86,756	31	36
NINCDS	2390	294,288	2238	230,361	93.6	78.3	2238	337,673	598	91,083	26.7	27
NIAID	1717	186,900	1616	146,684	94.1	78.5	1616	216,700	465	70,770	28.8	32.7
NIGMS	2458	257,409	2335	207,434	95	80.6	2335	300,215	810	124,359	34.7	41.4
NICHD	1920	189,377	1764	153,259	91.9	80.9	1764	225,175	467	64,379	26.5	28.6
NEI	690	68,647	657	56,527	95.2	82.3	657	85,849	331	41,856	50.4	48.8
NIEHS	407	42,958	363	35,074	89.2	81.6	363	49,741	111	16,203	30.6	32.6
NIA	760	90,152	582	64,147	76.6	71.2	582	90,444	177	28,425	30.4	31.4
NIAMSD	663	72,733	628	57,658	94.7	79.3	628	83,200	173	24,606	27.5	29.6
TOTAL,NIH	19646	2,266,743	17986	1,767,233	91.6	78	17986	2,597,705	5519	871,212	30.7	33.5

NOTE: In prior NIH submissions, the total eligible for funding included council recommended for approval plus carryovers from prior year that were eligible and considered for funding in the subsequent year. A policy decision has recently been made to change the way in which carryover is reported to ensure a greater degree of uniformity in data presentation among the NIH awarding units. As a result of this change, 1) in all years for which actual data is available, the total eligible for funding includes the council recommended for approval plus funded carryover from the prior year; and 2) for the current year and budget year estimates, the total eligible for funding includes only those applications recommended for approval by council.

Includes SBIR approved, recommended or funded.

H-7 (12)

NATIONAL INSTITUTES OF HEALTH
RESEARCH PROJECT APPLICATIONS REVIEWED AND FUNDED, 1987
(DOLLARS IN THOUSANDS)

-ESTIMATE-

	DIRECT COSTS ONLY						TOTAL COSTS					
	REVIEWED		COUNCIL RECOMMENDED		COUNCIL RECOMMENDATION RATE		TOTAL ELIGIBLE FOR FUNDING		FUNDED		AWARD RATE	
	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT	NUMBER	AMOUNT
NCI	3663	$505,631	3267	$388,205	89.2%	76.8%	3267	$595,068	874	$149,070	26.8%	25.1%
NHLBI	2915	393,672	2685	302,539	92.1	76.9	2685	450,629	802	145,635	29.9	32.3
NIDR	416	43,471	352	33,761	84.6	77.7	352	49,010	110	12,683	31.3	25.9
NIDDK	1969	225,000	1895	181,354	96.2	80.6	1895	263,508	566	82,627	29.9	31.4
NINCDS	2479	323,730	2389	262,705	96.4	81.1	2389	390,390	538	80,126	22.5	20.5
NIAID	1668	185,578	1576	145,525	94.5	78.4	1576	216,917	421	58,126	26.7	26.8
NIGMS	2335	251,926	2246	207,520	96.2	82.4	2246	302,326	689	100,867	30.7	33.4
NICHD	1928	195,616	1851	167,132	96	85.4	1851	248,162	456	62,826	24.6	25.3
NEI	721	75,784	699	63,660	96.9	84	699	98,520	250	33,869	35.8	34.4
NIEHS	450	51,379	417	42,640	92.7	83	417	60,855	105	15,301	25.2	25.1
NIA	730	90,579	579	68,632	79.3	75.8	579	97,032	145	23,502	25	24.2
NIAMSD	679	77,626	654	62,568	96.3	80.6	654	90,911	148	19,909	22.6	21.9
TOTAL,NIH	19953	2,419,944	18610	1,926,241	93.3	79.6	18610	2,863,328	5104	784,541	27.4	27.4

NOTE: In prior NIH submissions, the total eligible for funding included council recommended for approval plus carryovers from prior year that were eligible and considered for funding in the subsequent year. A policy decision has recently been made to change the way in which carryover is reported to ensure a greater degree of uniformity in data presentation among the NIH awarding units. As a result of this change, 1) in all years for which actual data is available, the total eligible for funding includes the council recommended for approval plus funded carryover from the prior year; and 2) for the current year and budget year estimates, the total eligible for funding includes only those applications recommended for approval by council.

Includes SBIR approved, recommended or funded.

DHHS - National Institutes of Health
1985 COLUMN OF 1987 CONGRESSIONAL

(In thousands)

Research Grants	NCI		NHLBI		NIDR		NIADDK		NINCDS		NIAID		NIGMS		NICHD		NEI		NIEHS		NIA		DRR		FIC		TOTAL	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Proj.:																												
Noncompeting	1907	$332,083	1732	$318,133	266	$31,198	1814	$259,765	1144	$148,144	1128	$166,627	1907	$259,990	898	$119,672	701	$84,646	234	$35,765	269	$49,727					12000	$1,805,750
Admin. supp.	(160)	7,747	(38)	1,226	(1)	70	(92)	7,847	(36)	3,412	(18)	667	(75)	2,998	(78)	3,732	(49)	1,348	(7)	443	(26)	989					(580)	30,479
Competing	999	167,633	901	158,203	131	15,859	786	104,756	722	105,978	540	70,728	987	133,845	469	64,200	367	47,230	108	16,424	209	30,895					6219	915,751
Subtot., C	999	167,633	901	158,203	131	15,859	786	104,756	722	105,978	540	70,728	987	133,845	469	64,200	367	47,230	108	16,424	209	30,895					6219	915,751
Subtot., RPG	2906	507,463	2633	477,562	397	47,127	2600	372,368	1866	257,534	1668	238,022	2894	396,833	1367	187,604	1068	133,224	342	52,632	478	81,611					18219	2,751,980
Research Ctrs:																												
Spec/comp.	58	84,957	60	84,112	13	13,000	45	35,011	40	30,133	18	5,590	15	9,235	43	27,559	28	5,765	15	15,101	12	9,513					347	319,976
GCRC																							78	$86,805			78	86,805
Biotech																							61	34,962			61	34,962
LASPR																							46	28,869			46	28,869
Gorgas																									1	$1,999	1	1,999
Subtotal	58	84,957	60	84,112	13	13,000	45	35,011	40	30,133	18	5,590	15	9,235	43	27,559	28	5,765	15	15,101	12	9,513	185	150,636	1	1,999	533	472,611
Other Res.:																												
Careers	127	6,799	356	22,101	47	2,907	246	15,370	204	10,993	78	4,058	16	609	113	5,962	18	1,001	24	1,340	79	4,813	6	324			1314	76,277
Organ sys.	1	935																									1	935
Clin. ed.	45	3,963																									45	3,963
Coop. cl.	271	50,822	16	1,796																							287	52,618
BRS																							728	95,733			728	95,733
MBRS		3,373		2,399		92		1,629		177		414				516		308		509		226	95	24,612			95	34,255
Other	58	3,679	74	10,428	76	1,335	39	2,375	30	1,944	30	743	28	2,334	21	1,044	35	1,211	12	439	63	1,896	89	16,865			555	44,293
Subtotal	502	69,571	446	36,724	123	4,334	285	19,374	234	13,114	108	5,215	44	2,943	134	7,522	53	2,520	36	2,288	142	6,935	918	137,534			3025	308,074
Total, RGs	3466	661,991	3139	598,398	533	64,461	2930	426,753	2140	300,781	1794	248,827	2953	409,011	1544	222,685	1149	141,509	393	70,021	632	98,119	1103	288,170	1	1,999	21777	3,532,725
Training																												
Indiv.	241	5,308	210	5,191	37	974	203	4,994	253	5,486	75	1,849	502	10,668	127	2,904	111	2,465	44	784	24	553	4	91			1831	41,267
Instit.	1223	25,489	1499	34,852	160	3,829	843	21,711	370	7,664	442	9,440	2894	47,053	575	10,958	109	2,766	439	7,718	203	4,058	35	984			8792	176,102
Total	1464	30,797	1709	39,623	197	4,803	1046	26,705	623	13,150	517	11,289	3396	57,721	702	13,862	220	5,231	483	8,502	227	4,611	39	1,075			10623	217,369
Contracts	415	143,142	214	56,737	21	4,696	31	9,885	76	14,163	74	18,672	5	1,234	114	23,080	42	7,123	177	55,611		11,557	3	3,103			1172	350,961
Intramural		197,838		61,487		19,864		37,215		48,123		51,142		784		35,862		15,466		53,459		20,440						541,690
RM&S		59,639		35,482		6,796		15,530		17,761		14,407		12,874		14,374		5,382		6,130		8,582		8,291		9,315		214,761
Control		63,774																										63,774
Construct.		6,500		3,300														3,300										13,100
Total, IRDs		1,163,701		795,027		100,620		536,088		393,978		344,337		481,624		309,823		178,011		193,723		143,309		302,639		11,314		4,934,394

National Library of Medicine	54,070
Office of the Director	34,177
Buildings and Facilities	15,675
Total, NIH	5,058,346

DHHS - National Institutes of Health
1986 APPROPRIATION

(In thousands)

Research Grants	NCI		NHLBI		NIDR		NIADDK		NINCDS		NIAID		NIGMS		NICHD		NEI		NIEHS		NIA		DRR		FIC		TOTAL	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Proj.:																												
Noncompeting	2090	$399,538	1818	$369,412	248	$28,976	1790	$274,269	1273	$188,114	1162	$174,615	1971	$290,228	891	$130,271	783	$101,469	247	$39,173	303	$60,130					17576	[illegible]
Admin. supp.	(152)	6,575	(35)	1,162			(79)	4,713	(33)	1,000	(16)	573	(17)	675	(40)	1,272	(45)	880	(10)	528	(8)	128					(435)	[illegible]
Competing	924	175,325	886	162,378	149	18,083	836	124,560	645	104,986	508	73,618	972	138,792	483	67,668	358	47,066	111	16,931	201	32,442					6073	[illegible]
Subtot., C	924	175,325	886	162,378	149	18,083	836	124,560	645	104,986	508	73,618	972	138,792	483	67,668	358	47,066	111	16,931	201	32,442					6073	[illegible]
Subtot., RPG	3014	581,438	2704	532,952	397	47,009	2626	403,542	1918	294,100	1670	248,806	2943	429,695	1374	199,211	1141	149,415	358	56,632	504	92,700					18649	[illegible]
Research Ctrs:																												
Spec/comp.	58	85,823	60	86,535	16	13,905	45	35,598	38	30,150	18	5,809	16	10,219	43	27,538	29	6,100	15	15,391	12	10,396					350	[illegible]
GCRC																							78	$89,896			78	[illegible]
Biotech																							61	35,632			61	[illegible]
LASPR																							46	30,346			46	[illegible]
Gorgas																									1	$1,999	1	[illegible]
Subtotal	58	85,823	60	86,535	16	13,905	45	35,598	38	30,150	18	5,809	16	10,219	43	27,538	29	6,100	15	15,391	12	10,396	185	155,874	1	1,999	536	[illegible]
Other Res.:																												
Careers	122	6,907	364	27,915	58	4,204	223	15,021	226	12,405	71	3,979	16	611	110	6,059	15	881	28	1,484	71	4,759	6	346			1310	[illegible]
Organ sys.	1	1,000																									1	[illegible]
Clin. ed.	52	4,700																									52	[illegible]
Coop. cl.	255	50,204	16	1,142					1	1,000																	272	[illegible]
BRS																							720	95,500			720	[illegible]
MBRS		3,400		2,500		117		1,600		200		460				589		315		371		373	92	24,951			92	[illegible]
Other	34	3,440	55	9,159	75	1,311	36	2,642	21	$1,871	11	877	21	$2,017	8	962	35	1,176	6	$423	14	1,079	76	12,487	155	4,622	547	[illegible]
Subtotal	464	69,651	435	35,716	133	5,632	259	19,263	248	15,476	82	5,316	37	2,628	118	7,610	50	2,378	34	2,278	85	6,211	894	133,284	155	4,622	2994	[illegible]
Total, Res	3536	736,912	3199	655,203	346	66,546	2930	458,403	2204	339,726	1770	259,931	2996	442,542	1535	234,359	1270	157,893	407	74,301	601	109,307	1079	289,158	156	6,621	22179	[illegible]
Training																												
Individual	204	4,626	234	6,031	50	1,250	158	3,905	208	4,501	85	2,156	345	7,678	103	2,550	108	2,615	38	710	33	782	3	84			1569	[illegible]
Institutional	1082	26,212	1476	34,175	162	3,312	1012	22,825	417	8,652	406	9,097	2894	50,043	571	11,351	100	2,616	439	7,792	207	4,725	36	991			8802	[illegible]
Total	1286	30,838	1710	40,206	212	4,562	1170	26,730	625	13,153	491	11,253	3239	57,721	674	13,901	208	5,231	477	8,502	240	5,507	39	1,075			10371	[illegible]
Contracts	451	139,706	189	53,080	35	4,686	40	$11,850	67	13,102	59	18,134	5	1;263	109	23,152	48	6,649	178	54,443	48	13,733	6	5,189			1235	[illegible]
Intramural		$194,102		$60,764		$19,996		58,758		48,615		51,350		875		$35,518		16,051		54,130		$20,885						[illegible]
RMS		59,484		35456		6,803		16,196		16,998		16,049		13,298		15,137		5,847		6,003		8,243		$8,400		$4,769		[illegible]
Control		63,878																										[illegible]
Construct.		2,000		3,300														3,300										[illegible]
Total, IRDs		1,226,920		848,009		102,593		571,937		431,594		356,717		515,699		322,067		194,971		197,379		157,675		303,822		11,390		[illegible]
National Library of Medicine																												[illegible]
Office of the Director																												[illegible]
Buildings and Facilities																												[illegible]
Total, NIH																												[illegible]

DHHS - National Institutes of Health
1986 ADJUSTED APPROPRIATION WITH SEQUESTRATION

H-8 (3)

(In thousands)

Research Grants	NCI No.	NCI Amount	NHLBI No.	NHLBI Amount	NIDR No.	NIDR Amount	NIADDK No.	NIADDK Amount	NINCDS No.	NINCDS Amount	NIAID No.	NIAID Amount	NIGMS No.	NIGMS Amount	NICHD No.	NICHD Amount	NEI No.	NEI Amount	NIEHS No.	NIEHS Amount	NIA No.	NIA Amount	DRR No.	DRR Amount	FIC No.	FIC Amount	TOTAL No.	TOTAL Amount
Research Proj.:																												
Noncompeting	2090	$382,336	1818	$353,528	248	$27,682	1790	$262,475	1273	$180,025	1162	$167,106	1971	$277,748	891	$124,669	783	$97,106	247	$37,489	303	$57,544					12576	[illegible]
Admin. supp.	(152)	6,292	(35)	1,112			(79)	4,510	(33)	957	(16)	548	(17)	646	(40)	1,217	(45)	842	(10)	505	(8)	123					(435)	[illegible]
Competing	924	167,955	886	155,423	149	17,309	836	119,342	645	$100,464	508	70,477	972	132,874	483	64,779	358	45,046	111	16,203	201	31,104					6073	[illegible]
Subtot., C	924	167,955	886	155,423	149	17,309	836	119,342	645	100,464	508	70,477	972	132,874	483	64,779	358	45,046	111	16,203	201	31,104					6073	[illegible]
Subtot., RPG	3014	556,583	2704	510,063	397	44,991	2626	386,327	1918	281,446	1670	238,131	2943	411,268	1374	190,665	1141	142,994	358	54,197	504	88,771					18649	[illegible]
Research Ctrs:																												
Spec/comp.	57	82,132	60	82,814	16	13,307	45	34,067	38	28,853	18	5,559	15	9,780	43	26,355	29	5,838	15	14,729	12	9,949					348	[illegible]
GCRC																							78	$86,031			78	[illegible]
Biotech																							61	34,100			61	[illegible]
LASPR																							46	29,041			46	[illegible]
Gorgas																									1	1,913	1	[illegible]
Subtotal	57	82,132	60	82,814	16	13,307	45	34,067	38	28,853	18	5,559	15	9,780	43	26,355	29	5,838	15	14,729	12	9,949	185	149,172	1	1,913	534	[illegible]
Other Res.:																												
Careers	117	6,610	364	21,930	55	4,023	212	14,375	216	11,872	68	3,809	15	585	105	5,798	15	849	27	1,420	70	4,554	6	331			1270	[illegible]
Organ sys.	1	977																									1	[illegible]
Clin. ed.	52	4,478																									52	[illegible]
Coop. cl.	228	48,045	16	1,093					1	957																	245	[illegible]
BRS																							713	91,393			713	[illegible]
MBRS		3,254		2,392		112		1,531		191		440				564		301		355		357	92	23,878			92	[illegible]
Other	33	3,292	55	8,766	72	1,255	34	2,529	19	$1,786	11	839	17	$1,920	8	921	35	1,125	6	$404	11	1,033	76	11,950	153	4,423	530	[illegible]
Subtotal	431	66,656	435	34,181	127	5,390	246	18,435	236	14,806	79	5,088	32	2,505	113	7,283	50	2,275	33	2,179	81	5,944	887	127,552	153	4,423	2903	[illegible]
Total, RGs	3502	705,371	3199	627,058	540	63,689	2917	438,829	2192	325,105	1767	248,778	2990	423,553	1530	224,303	1220	151,107	406	71,105	597	104,664	1072	276,724	154	6,336	22086	3,666,622
Training																												
Individual	195	4,427	217	5,772	48	1,196	155	3,838	199	4,307	69	1,722	312	6,831	99	2,440	108	2,503	36	679	32	748	3	81			1473	[illegible]
Institutional	1036	25,085	1410	32,705	156	3,170	966	21,743	399	8,280	394	9,048	2796	48,408	546	10,863	100	2,504	439	7,457	198	4,522	34	948			8474	[illegible]
Total	1231	29,512	1627	38,477	204	4,366	1121	25,581	598	12,587	463	10,770	3108	55,239	645	13,303	208	5,007	475	8,136	230	5,270	37	1,029			9947	[illegible]
Contracts	438	133,732	189	50,797	33	4,484	39	$11,314	67	12,539	57	17,354	5	1,209	106	22,156	48	6,363	168	52,102	46	13,142	6	4,965			1202	[illegible]
Intramural		$185,704		$58,150		$19,135		56,231		46,532		49,133		837		$33,981		15,360		51,801		$19,986						[illegible]
RM&S		56,911		33904		6,508		15,500		16,261		15,358		12,726		14,496		5,591		5,743		7,884		$8,034		$4,557		[illegible]
Control		61,131																										61,131
Construct.		1,914		3,158														3,158										[illegible]
Total, IRDs		1,174,275		811,544		98,181		547,455		413,024		341,393		493,564		308,229		186,586		188,887		150,946		290,752		10,893		5,015,729

National Library of Medicine	[illegible]
Office of the Director	[illegible]
Buildings and Facilities	[illegible]
Total, NIH	[illegible]

DHHS - National Institutes of Health
1986 COLUMN OF 1987 CONGRESSIONAL

(In thousands)

Research Grants	NCI No.	NCI Amount	NHLBI No.	NHLBI Amount	NIDR No.	NIDR Amount	NIADDK No.	NIADDK Amount	NINCDS No.	NINCDS Amount	NIAID No.	NIAID Amount	NIGMS No.	NIGMS Amount	NICHD No.	NICHD Amount	NEI No.	NEI Amount	NIEHS No.	NIEHS Amount	NIA No.	NIA Amount	DRR No.	DRR Amount	FIC No.	FIC Amount	TOTAL No.	TOTAL Amount
Research Projs.:																												
Noncompeting	2090	$382,336	1818	$351,528	248	$27,682	1790	$262,475	1273	$180,025	1162	$168,697	1971	$278,918	891	$123,919	783	$95,072	247	$37,489	303	$57,544					12576	$1,961,[illegible]
Admin. supp.	(152)	6,292	(35)	1,112			(79)	4,510	(33)	957	(16)	548	(17)	633	(40)	1,217	(45)	842	(10)	505	(8)	123					(435)	16,[illegible]
Competing	850	161,155	817	143,954	149	17,309	737	111,362	597	$90,910	446	67,373	810	124,359	467	64,379	331	41,856	111	16,203	177	28,425					5492	867,285
Subtot., C	850	161,155	817	143,954	149	17,309	737	111,362	597	90,910	446	67,373	810	124,359	467	64,379	331	41,856	111	16,203	177	28,425					5492	867,285
Subtot., RPG	2940	549,783	2635	496,594	397	44,991	2527	378,347	1870	271,892	1608	236,618	2781	403,910	1358	189,515	1114	137,770	358	54,197	480	86,092					18068	2,8[illegible]
Research Ctrs:																												
Spec/comp.	57	82,132	60	82,814	16	13,307	45	34,067	38	28,853	18	5,559	15	9,780	43	26,355	29	5,838	15	14,729	12	9,949					348	[illegible]
GCRC																							78	$86,031			78	[illegible]
Biotech																							61	34,100			61	[illegible]
LASFR																							46	29,041			46	[illegible]
Gorgas																									1	$1,913	1	1,913
Subtotal	57	82,132	60	82,814	16	13,307	45	34,067	38	28,853	18	5,559	15	9,780	43	26,355	29	5,838	15	14,729	12	9,949	185	149,172	1	1,913	534	[illegible]
Other Res.:																												
Careers	117	6,615	364	21,930	55	4,023	212	14,375	216	11,872	68	3,809	15	585	105	5,798	15	949	27	1,420	70	4,554	6	331			1270	[illegible]
Organ sys.	1	957																									1	[illegible]
Clin. ed.	52	4,478																									52	[illegible]
Coop. cl.	228	48,045	16	1,093					1	957																	245	[illegible]
ARC																							713	91,193			713	[illegible]
MARS		3,254		2,392		112		1,531		191		440				564		201		355		331	92	23,818			92	[illegible]
Other	33	3,297	55	8,766	72	1,255	34	2,529	19	$1,786	11	839	17	$1,920	8	921	35	1,125	6	$404	11	1,033	76	11,950	153	4,423	530	[illegible]
Subtotal	431	66,656	435	34,181	127	5,390	246	18,435	236	14,806	79	5,088	32	2,505	113	7,283	50	2,275	33	2,179	81	5,944	887	127,552	153	4,423	2903	[illegible]
Total, RGs	3428	698,571	3130	615,589	540	63,688	2818	430,849	2144	315,551	1705	247,265	2828	416,195	1514	223,153	1193	145,883	406	71,105	573	101,985	1072	276,724	154	6,336	21505	3,612,894
Training																												
Indiv.	195	4,427	217	5,772	48	1,196	155	3,838	199	4,307	69	1,722	312	6,831	99	2,440	108	2,503	36	679	32	748	3	81			1473	[illegible]
Instit.	1036	25,085	1410	32,705	156	3,170	966	21,743	399	8,280	394	9,048	2796	48,408	546	10,863	100	2,504	439	7,457	198	4,522	34	948			8474	[illegible]
Total	1231	29,512	1627	38,477	204	4,366	1121	25,581	598	12,587	463	10,770	3108	55,239	645	13,303	208	5,007	475	8,136	230	5,270	37	1,029			9947	[illegible]
Contracts	438	133,732	189	50,797	33	4,484	39	$11,314	67	12,539	57	17,354	5	1,709	106	22,156	48	6,363	168	52,102	46	13,142	6	4,965			1202	[illegible]
Intramural		$185,704		$50,150		$17,135		56,271		46,532		49,133		837		$33,981		15,360		51,801		$19,986						[illegible]
RM&S		56,911		33904		6,508		15,500		16,261		15,358		12,726		14,486		5,591		5,743		7,884		$8,034		$4,557		[illegible]
Control		61,131																										61,131
Construct.		1,914		3,158														3,158										[illegible]
Total, IRDs		1,167,475		800,075		98,181		539,475		403,470		339,880		486,206		307,079		181,362		188,887		148,267		290,752		10,893		4,962,002

National Library of Medicine	[illegible]
Office of the Director	[illegible]
Buildings and Facilities	[illegible]
Total, NIH	5,067,347

DHHS - National Institutes of Health
1987 CONGRESSIONAL JUSTIFICATION

H-8 (5)

(In thousands)

Research Grants	NCI		NHLBI		NIDR		NIDDKD		NINCDS		NIAID		NIGMS		NICHD		NEI		NIEHS		NIA		NIAMSD		DRR		FIC		TOTAL	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Proj.:																														
Noncompeting	2050	$381,489	1803	$352,109	269	$30,561	1361	$207,080	1313	$188,941	1178	$171,293	2082	$292,509	913	$125,465	853	$101,642	229	$37,098	345	$60,618	389	$54,702					12785	$2,003,507
Admin. supp.	(152)	6,575	(35)	1,162	--	---	(46)	1,436	(23)	668	(16)	524	(17)	703	(40)	1,340	(38)	1,750	(10)	514	(8)	128	(14)	400					(399)	15,200
Competing	874	149,070	802	145,635	110	12,683	566	82,627	538	80,126	421	58,126	689	100,867	456	62,826	250	33,869	105	15,301	145	23,502	148	19,909					5104	784,541
Subtot., C	874	149,070	802	145,635	110	12,683	566	82,627	538	80,126	421	58,126	689	100,867	456	62,826	250	33,869	105	15,301	145	23,502	148	19,909					5104	784,541
Subtot., RPG	2924	537,134	2605	498,906	379	43,244	1927	291,143	1851	269,735	1599	229,943	2771	394,079	1369	189,631	1103	137,261	334	52,913	490	84,248	537	75,011					17889	2,803,248
Research Ctrs.:																														
Spec./Comp.	57	82,282	60	75,757	16	11,790	31	23,682	38	26,371	14	3,734	11	6,559	43	26,217	29	5,400	15	14,482	12	9,812	14	9,317					340	295,403
[illegible]																									76	86,082			76	86,082
Biotech																									60	33,898			60	33,898
[illegible]																									46	29,905			46	29,905
[illegible]																											1	$1,934	1	1,934
Subtotal	57	82,282	60	75,757	16	11,790	31	23,682	38	26,371	14	3,734	11	6,559	43	26,217	29	5,400	15	14,482	12	9,812	14	9,317	182	149,885	1	$1,934	523	447,222
Other Res.:																														
Careers	122	6,907	364	21,906	58	4,204	160	10,692	216	11,872	68	3,979	18	677	105	5,798	12	625	25	1,322	68	4,512	48	3,409	6	346			1270	76,249
Organ Sys.	1	800																											1	800
Cancer Ed.	39	2,400																											39	2,400
Coop. Cl.	239	49,884	16	1,035					1	957																			256	51,876
BRS																									154	32,883			154	32,883
MBRS		3,400		2,267		117		1,196		191		460				564		301		355		307		335	92	24,149			92	33,642
Other	30	3,161	55	8,489	65	1,135	26	1,405	19	1,892	11	914	2	1,865	8	921	20	850	6	420	10	829	8	1,124	76	12,122	153	4,557	489	39,684
Subtotal	431	66,552	435	33,697	123	5,456	186	13,293	236	14,912	79	5,353	20	2,542	113	7,283	32	1,776	31	2,097	78	5,648	56	4,868	328	69,500	153	4,557	2301	237,534
Total, RGs	3812	685,968	3100	608,360	518	60,490	2144	328,118	2125	311,018	1692	239,030	2802	403,180	1525	223,131	1164	144,437	380	69,492	580	99,708	607	89,196	510	219,385	154	6,491	20713	3,488,004
Training																														
Indiv.	189	4,292	203	5,140	42	1,050	116	2,856	199	4,307	55	1,414	194	4,484	95	2,351	98	2,388	33	670	30	713	35	881	3	84			1292	30,630
Instit.	1004	24,318	1297	28,629	162	3,312	719	16,188	399	8,280	320	7,569	2603	48,432	539	10,749	92	2,388	409	7,336	165	4,396	222	4,986	35	991			7966	167,574
Total	1193	28,610	1500	33,769	204	4,362	835	19,044	598	12,587	375	8,983	2797	52,916	634	13,100	190	4,776	442	8,006	195	5,109	257	5,867	38	1,075			9258	198,204
Contracts	435	133,960	189	51,919	34	4,586	30	8,393	60	11,529	47	15,235	5	1,263	115	22,156	55	7,215	168	52,045	42	12,590	6	2,536	6	5,031			1192	328,458
Intramural		190,291		56,065		20,303		49,980		47,804		51,492		875		35,746		16,723		52,647		20,250		6,181						548,357
RMS		58,129		35,584		6,741		13,436		16,413		15,811		13,299		14,986		6,050		5,805		8,172		2,951		8,701		4,814		210,894
Cntrl		61,131																												61,131
Construct		---		---														---												---
Total, BIDs		1,158,089		785,697		96,482		418,971		399,351		330,551		471,533		309,119		179,201		187,995		145,829		106,733		234,192		11,305		4,835,048

National Library of Medicine	56,408
Office of the Director	36,701
Buildings and Facilities	8,000
Total, NIH	4,936,157

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUMMARY

Budgeted Full-Time Permanent Employment, Fiscal Years 1986 and 1987

Appropriation	FY 1986 Authorized Positions	FY 1986 Estimated FTE[1]	FY 1986 On Duty 12/31/85	FY 1986 Anticipated On-Duty 09/30/86	FY 1987 Positions Requested	FY 1987 Estimated FTE[1]	FY 1987 Anticipated On-Duty 09/30/87
Public Health Service:							
Health Resources and Services Administration:							
Health Resources and Services.............	3,244	3,294	2,690	2,863	2,208	2,489	2,096
Centers for Disease Control.....................	3,890	4,015	3,823	3,890	3,890	4,015	3,890
National Institutes of Health.....................	12,172	12,649	10,181	10,283	12,172	12,649	10,302
Alcohol, Drug Abuse and Mental Health Administration:							
Alcohol, Drug Abuse and Mental Health........	1,004	1,501	1,022	1,004	1,004	1,501	1,004
Office of the Assistant Secretary for Health.......	1,291	1,379	1,258	1,215	1,296	1,384	1,241
Subtotal, PHS (Labor-HHS)..............	21,601	22,838	18,974	19,255	20,570	22,038	18,533
Food and Drug Administration..................	6,928	6,942	6,760	6,600	6,928	6,942	6,600
Health Resources and Services Administration:							
Indian Health Service....	11,589	10,817	10,257	10,218	11,589	10,400	10,162
Total, PHS	40,118	40,597	35,991	36,073	39,087	39,380	35,295

Appropriation	FY 1986				FY 1987		
	Authorized Positions	Estimated FTE [1]	On Duty 12/31/85	Anticipated On-Duty 09/30/86	Positions Requested	Estimated FTE [1]	Anticipated On-Duty 09/30/87
Health Care Financing Administration..........	4,188	3,881	3,809	3,808	4,045	3,757	3,702
Social Security Administration..............	75,670	71,546	71,274	71,317	73,000	69,484	68,317
Office of Refugee Resettlement.............	80	84	60	84	77	77	77
Office of Child Support Enforcement.....	318	307	300	290	318	297	283
Human Development Services................	1,151	1,125	1,060	1,105	1,105	1,105	1,105
Office of Community Services................	57	57	51	57	36	36	36
Departmental Management...	4,341	3,785	3,860	3,732	4,025	3,718	3,697
Subtotal, HHS (Labor-HHS)	107,406	103,623	99,388	99,648	103,176	100,512	95,750
Office of Consumer Affairs	34	22	28	5	6	5	5
Total, HHS	125,957	121,404	116,433	116,471	121,699	117,859	112,517

[1] FTE levels apply to total employment; includes part-time and temporary, as well as full-time permanent employees.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUMMARY
Fiscal Year 1986 Obligations as of December 31, 1985
(In Thousands of Dollars)

OPDIV/Agency	Available for Obligation	Available for Obligation less Reserve	Estimated Obligations as of December 31, 1985	Unobligated Balance as of December 31, 1985
Public Health Service:				
Health Resources and Services Administration:				
Health Resource and Services......	$ 1,611,647	$ 1,561,643 1/	$ 211,672	$ 1,349,971
Centers for Disease Control..........	498,167	443,291 2/	97,718	345,573
National Institutes of Health..............................	1,310,043	1,310,043	971,077	338,966
Alcohol, Drug Abuse, and Mental Health Administration......	1,099,090	1,089,501	156,369	933,132
Office of the Assistant Secretary for Health..............	111,605 1/	106,081 3/	15,852	90,231
Subtotal, PHS (Labor-HHS)	4,630,552	4,510,561	1,452,688	3,057,873
Food and Drug Administration.........	413,708	413,510	105,669	307,841
Health Resources and Services Administration:				
Indian Health Services.............	958,609	958,260 4/	163,736	794,554
Total, PHS............................	6,002,869	5,882,331	1,722,093	4,160,268
Health Care Financing Administration......................	44,680,120 5/	44,665,765	10,809,559	33,870,566
Social Security Administration.. 6/ ..	29,951,080	29,690,761 7/	11,013,217	18,677,544
Office of Refugee Resettlement........	427,861	321,912 8/	63,217	258,695
Office of Human Development Services..............................	5,768,229	5,768,229	1,204,386	4,563,842
Office of Community Services..........	85,679	----	85,508	170
Departmental Management...............	266,188	251,549 9/	53,126	198,423
Subtotal, HHS (Labor-HHS)............	85,809,709	85,208,777	24,681,701	60,627,113
Office of Consumer Affairs............	2,038	1,953	397	1,556
Total, HHS...........................	$87,184,064	$86,582,500	$24,951,503	$61,731,064

1/ Excludes Gramm-Rudman-Hollings sequestration of $49,719,000 and Section 515 withholding of $285,000.
2/ Includes $447,000 receipts from non-federal sources and $35,840,000 unobligated balance brought forward.
3/ Includes an appropriation transfer of $1,050,000 from the Federal Hospital Insurance and the Federal Supplementary Medical Insurance Trust Funds, and funds made available for obligation pursuant to the Health Services Amendments of 1985 (P.L. 99-117) and the Health Research Extension Act (P.L. 99-158).
4/ Excludes Gramm-Rudman-Hollings sequestering and Section 515 withholding.
5/ Excludes Gramm-Rudman-Hollings reduction of $54,433 and proposed rescission of $9,401.
6/ Include reimbursements of $2,013,781,303 and Gramm-Rudman-Hollings reductions of $256,923,000.
7/ Excludes contingency reserve of $138,765,000, consultant services withholding of $226,000 and planned carryover of $121,288,000.
8/ Excludes Gramm-Rudman-Hollings reduction of $18,398,000 and proposed recission of $87,551,000.
9/ Excludes Gramm-Rudman-Hollings reduction of $10,197 and proposed rescission of $4,527.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUMMARY

Entertainment Fund Authorization for Fiscal Year 1986 and Amount Expended

Appropriation	Authorized for FY 1986	Expended in FY 1986*	FY 1987 Budget Request
Public Health Service:			
Office of the Assistant Secretary for Health.............	$ 9,500	$ 1,224	$ 9,500
Health Care Financing Administration..................	2,000	---	2,000
Social Security Administration.....	5,000	1,051	5,000
Departmental Management...........	7,500	2,370	7,500
Total, HHS......................	$ 24,000	$ 4,645	$ 24,000

*October 1, 1985 through December 31, 1985

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUMMARY

New Programs in 1987 Budget

Appropriation Program	1987 Budget Request
Public Health Service:	
Health Resources and Services Administration:	*
Expanding Primary Care Block Grant........................	$565,100,000
Centers for Disease Control:	
Research and Training: Infant Mortality.................	1,750,000
National Institutes of Health:	
National Institutes of Arthritis and Musculoskeletal and Skin Diseases........................	106,733,000
Subtotal, PHS...............	673,583,000
Office of Human Development Services:	
Human Development Services:	
Family Crisis and Protective Services........................	30,500,000
Total, HHS............................	$704,083,000

DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUMMARY
Analysis of Unobligated Carryover Balances
Fiscal Years 1985, 1986 and 1987

OPDIV/ Agency	Balance end of 1985	Balance end of 1986	Balance end of 1987
Public Health Service:			
Health Resources and Services Administration:			
Health Resources and Services......	$ 81,037,078	$ 66,020,000	$ 59,578,000
Centers for Disease Control..........	35,839,545	---	---
National Institutes of Health........	11,247,000	---	---
Office of the Assistant Secretary for Health..........................	5,978,715	3,078,000	91,000
Subtotal, PHS, (Labor,HHS).............	134,102,138	69,098,000	59,669,000
Health Resources and Services Administration:			
Indian Health Service..............	54,635,229	1,689,394	1,689,394
Total, PHS.............................	188,737,567	70,787,394	61,358,394
Health Care Financing Administration 1/	307,215	---	---
Social Security Administration 1/	29,122,147,000	26,755,880,000	41,164,639,000
Office of Refugee Resettlement.........	3,196,000	---	---
Office of Child Support Enforcement....	77,518	117	---
Office of Human Development Services...	62,084,606	30,985,254	15,985,254
Office of Community Services...........	16,298,862	---	---
Subtotal, HHS (Labor-HHS)..............	29,338,213,539	26,855,963,371	41,240,293,254
Total, HHS.............................	$29,392,843,768	$26,857,652,765	$41,241,982,648

1/ Amounts shown for HCFA and SSA are primarily from trust funds.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUMMARY

Obligated but Unexpended Balances, End of Fiscal Year
(Dollars in thousands)

	1985	1986	1987
Public Health Service:			
Health Resources and Services Administration: Health Resources and Services...	$ 959,408	$ 898,810	$ 768,276
Centers for Disease Control........	181,371	168,245	156,626
Alcohol, Drug Abuse and Mental Health Administration............	263,811	285,013	200,283
National Institutes of Health.....	3,298,720	3,456,807	3,199,655
Office of the Assistant Secretary for Health............	29,200	30,054	30,952
Subtotal, PHS (Labor-HHS)........	4,732,520	4,838,929	4,355,792
Food and Drug Administration......	88,672	91,096	87,851
Health Resources and Services Administration: Indian Health Services...........	211,735	278,138	270,460
Total, PHS......................	5,012,927	5,208,163	4,714,103
Health Care Financing Administration.....................	374,754	375,587	376,541
Social Security Administration.......	15,796,679	16,820,117	18,042,144
Office of Refugee Resettlement	210,376	142,484	173,696
Office of Child Support Enforcement.	16,210	15,898	16,210
Human Development Services...........	1,398,960	1,355,908	1,376,630
Office of Community Services.........	127,745	62,794	4,642
Departmental Management..............	49,571	44,780	37,953
Subtotal, HHS, (Labor-HHS).........	22,634,771	23,656,497	24,383,608
Office of Consumer Affairs..........	299	425	295
Total, HHS........................	$22,985,567	$24,026,156	$24,742,214

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH RESOURCES AND SERVICES

1987 Legislative Programs

(In thousands of dollars)

Appropriation/Program	Authority	Outlays
Health Resources and Services		
New Legislative Proposals		
A. Transmitted with the Budget:		
1. Primary Care Block Grants.....	$190,100,000	$81,743,000
Subtotal, Transmitted with Budget.	190,100,000	81,743,000
Extension of Expiring Legislation		
1. National Health Service Corps National Health Service Field Program (PHS Act, Sec. 331-338)......	46,996,000	47,804,000
2. Community Health Centers......	375,000,000	161,250,000
Subtotal, Extension of Expiring Legislation....................	421,996,000	209,054,000
Transfers Requiring Legislation............	N/A	N/A
Total Health Resources and Services........	$612,096,000	$290,797,000

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OPDIV

1987 Legislative Programs

(In thousands of dollars)

Alcohol, Drug Abuse and Mental Health	Budget Authority	Outlays
1. General Mental Health:		
a. Research:		
General-Section 301 of the Public Health Service Act (PHSA)...........................	Indefinite	$206,887
b. Planning & Demonstrations		
State Planning - PHSA Section 504.......................	Indefinite	3,108
Community Support - PHSA Section 504.......................	$20,000,000	
c. Protection and Advocacy 1/........	---	---
d. Training:		
Clinical-PHSA Section 303.........	Indefinite	18,574
Research-PHSA Section 472 2/......		
-PHSA Section 301.........	---	
e. Direct Operations:		
PHSA Section 301.....................	Indefinite	32,887
2. Drug Abuse		
a. Research:		
PHSA Section 301..................	Indefinite	69,677
PHSA Section 517..................	Expired	
b. Training:		
Research-PHSA Section 472 2/......	Expired	1,485
PHSA Section 301.........	---	
c. Direct Operations:		
PHSA Section 301..................	Indefinite	15,981
3. Alcohol		
a. Research:		
PHSA Section 301..................	Indefinite	51,051
PHSA Section 513..................	Expired	
b. Training:		
Research-PHSA Section 472 2/......	Expired	1,056
PHSA Section 301.........	---	
c. Direct Operations:		
PHSA Section 301..................	Indefinite	10,961
4. Buildings and Facilities		
PHSA Section 301..................	Indefinite	1,059

Alcohol, Drug Abuse and Mental Health	Budget Authority	Outlays
5. Program Management:		
PHSA Section 301..............	Indefinite	7,420
6. Block Grant:		
PHSA Section 1911.............	576,000,000	489,179
Total Obligations......	---	$909,325
Total obligations against definite authorizations.....................	$596,000,000	

1/ Funds appropriated pending enactment of authorizing legislation.
2/ Shared authorization with NIH and HRSA.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

1987 Legislative Programs

(In thousands of dollars)

Public Health Service Management

Extension of Expired Legislation:	Budget Authority	Outlays
1. Adolescent Family Life..............	$14,722	$15,681
Total, Extension of Expired Legislation...........................	$14,722	$15,681

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH CARE FINANCING ADMINISTRATION

1987 Legislative Programs

(In thousands of dollars)

Appropriation/Program	Budget Authority	Outlays
Federal Hospital Insurance		
1. Reduce Indirect Medical Education (Eliminate doubling of reimbursement under TEFRA)	N/A	-990,000
2. Home Health copayments (Apply cost-sharing at a rate of 1 percent of inpatient hospital deductible)	N/A	-100,000
3. Working Aged and Disabled (Make Medicare a secondary payer when beneficiaries or their spouse have group health insurance coverage)	N/A	-415,000
4. Begin Medicare coverage on first day of month following the month in which age 65 is attained.	N/A	-180,000
5. Voluntary Voucher (build on HMO/CMP experience with voucher based on 95 percent of the AAPCC)	N/A	33,000

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH CARE FINANCING ADMINISTRATION

1987 Legislative Programs

(In thousands of dollars)

Appropriation/Program	Budget Authority	Outlays
Federal Supplementary Medical Insurance		
1. Dynamic Deductible (indexed to Medicare Economic Index and rounded to next higher $1)	N/A	-310,000
2. Freeze Clinical Laboratory Fees (eliminate CPI update)	N/A	-55,000
3. Extend Medicare as Secondary Payer for Working Aged over age 69.	N/A	-125,000
4. Begin Medicare Coverage on First Day of month following the month in which age 65 is attained	N/A	-85,000
5. Voluntary Voucher (build on HMO/CMP experience with voucher based on 95 percent of the AAPCC)	N/A	17,000

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH CARE FINANCING ADMINISTRATION

1987 Legislative Programs

(In thousands of dollars)

Appropriation/Program	Budget Authority	Outlays
6. Reimpose the coinsurance for ambulatory surgical center facility services	N/A	-10,000
7. Increase the Part B Premium (gradually increase the premium to cover 35 percent of estimated program costs over 5 years)	N/A	-725,000
Payments to the Health Care Trust Funds		
1. Net impact of legislative changes (impact on appropriation of both Part A and Part B legislative proposals)	-1,299,000	-1,299,000

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH CARE FINANCING ADMINISTRATION

1987 Legislative Programs

(In thousands of dollars)

Appropriation/Program	Budget Authority	Outlays
To be Transmitted Later:		
Grants to States for Medicaid		
1. Limit Federal share of Medical Assistance Payments in FY 1987 and constrain future years to medical care price index	-1,182,000	-1,182,000
2. Establish one-time hardship pool	+300,000	+300,000
3. Reform Federal matching rates for Medicaid administration expenditures	-260,000	-260,000
4. Transfer of funds to the Refugee Program	-30,237	-30,237

Department of Health and Human Services
Office of Refugee Resettlement
1987 legislative Programs
(in thousands of dollars)

Appropriation/Program	Budget Authority	Outlays
Refugee and Entrant Assistance Extension of Expiring Legislation*- The Refugee Act of 1980	$373,998	$342,786
Subtotal, Extension of Expiring Legislation	$373,998	$342,786
Total, Appropriation	$373,998	$342,786

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* The Refugee Act of 1980, as amended, expired September 30, 1983. Congress has not enacted reauthorizing legislation; the program, since FY 1984, has been operating under authority of various Continuing Resolutions. Due to uncertainties of the provisions of any legislative extension for the Refugee program, ORR is reporting this program for FY 1987 on the basis of a simple extension of the previously expired legislation at this time.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF CHILD SUPPORT ENFORCEMENT

Legislative Proposals

($000)

	BA	Outlays
Child Support Enforcement		
New Legislative Proposals		
B. Proprosed for Later Transmittal		
1. Revise matching rate for State and local administrative costs to reduce Federal match................	-$41,000	-$41,000
Total (Appropriation)........	-$41,000	-$41,000

Department of Health and Human Services

Office of Human Development Services

1987 Legislative Programs
(in thousands of dollars)

Appropriation/Program		Budget Authority	Outlays
Human Development Services			
1. Head Start		$1,075,059	$1,078,014
2. Family Crisis and Protective Services		30,500	6,710
3. Administration for Native Americans		27,300	28,411
	Subtotal	1,130,859	1,113,135
Family Social Services			
1. Foster Care		544,310	535,742
	Total	$1,677,169	$1,648,877

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Human Development Services

Identification of 1987 Appropriation Language Provisions Earmarks, etc., which Modify or Go Beyond Authorizing Legislation

Language Provision	Explanation
Human Development Services	
...Provided that with regard to projects funded under the Head Start Act, grantees shall be considered as educational institutions within the meaning 3304(a)(6)(A) of the Federal Unemployment Training Act.	Language added to clarify the status of Head Start projects to preclude staff from drawing unemployment benefits during summer months.
Provided further, $76,349,000 shall be the maximum amount available for Indian and migrant Head Start programs and for Fiscal Year 1987.	Earmark assures that all Head Start programs will be treated equally. Without this language, Indian and migrant projects would be entitled to increases whereas other Head Start projects would not.
Family Social Services	
...of which not to exceed $1,400,000 will be available to carry out Title II of Public Law 95-266 (adoption opportunities:	Language added to limit the amount available for Adoption Opportunities, consistent with policy to limit spending for discretionary activities.
Provided, That for purposes of this appropriation, references to Fiscal Year 1985 in sections 474(b) and 474(c) of the Social Security Act, and in sections 102(a)(1) and 102(c) of Public Law 96-272, are deemed to be references to Fiscal Year 1987, and the term "$266,000,000" in section 474(b)(2) (A)(i) of the Social Security Act is deemed to read $200,000,000:	Language is added to reduce the child welfare services amounts necessary to trigger the cap on Foster Care. Without this language, the cap on Foster Care would not be triggered until Child Welfare Services reach $266,000,000. The Administration wishes to trigger the Foster Care cap without increasing Child Welfare Services appropriations.

Provided further, That allotments made under section 474(b)(3)(A) for Fiscal Year 1987 will be the lesser of 105 percent of the allotment for Fiscal Year 1986 or the amount of the allotment for Fiscal Year 1986 increased by the ratio of (i) the Consumer Price Index prepared by the Department of Labor, and used in determing cost-of-living adjustments under section 215(i) of the Act for the second quarter of Fiscal Year 1986, to (ii) such index for the second quarter of Fiscal Year 1985.

Language added to reduce the increase of allotments from the lesser of 110 percent of the 1986 allotment or twice the Consumer Price Index. Without this language States would be entitled to higher allotments.

HEALTH RESOURCES AND SERVICES
Language Analysis

Language Provision	Explanation
Provided further, That not to exceed $10,000,000, derived in accordance with 31 U.S.C. 9701, is to be credited to this appropriation.	HRSA proposes to initiate user fees on the qualification and monitoring of Health Maintenance Organizations and the eligibility determination for Comprehensive Medical Plans and Hill-Burton and HUD 242 loan applications and modifications.
Provided, That this appropriation shall be available for payment of the costs of medical care, related expenses, and burial expenses hereafter incurred by or on behalf of any person who has participated in the study of untreated syphilis initiated in Tuskegee, Alabama, in 1932, in such amounts and subject to such terms and conditions as prescribed by the Secretary of Health and Human Services and for payment, in such amounts and subject to such terms and conditions, of such costs and expenses hereafter incurred by or on behalf of such person's wife or offspring determined by the Secretary to have suffered injury or disease from syphilis contracted from such person.	There is no authorizing legislation for this provision. It represents a moral obligation of the Department.
Provided further, That when the Department of Health and human Services administers or operates an employee health program for any Federal department or agency, payment for the full estimated cost shall be made by way of reimbursement or in advances to this appropriation.	The Economy Act of 1932 authorized the crediting of reimbursements to regular appropriation accounts and the crediting of advances to special funds; however, this provision authorizes the crediting of both reimbursements and advances to a regular appropriation account.

Provided further, That one of the funds made available by this Act shall be used to provide special retention pay (bonuses) under paragraph (4) of 37 U.S.C. 302(a) to any regular or reserve officer of the Public Health Service for any period during which the officer is providing obligated service under section 338B (or under former sections 225(e) or 752) of the Public Health Service Act except that this proviso shall not apply to any period of service covered by an agreement entered into by an officer under 37 U.S.C. 302(c)(1) before the date of enactment of Public Law 97-377.	This language repeals the payment of special retention pay to NHSC Commissioned medical officers for any period during which the officers are providing obligated scholarship service, excluding those covered by an agreement entered into prior to the enactment of Public Law 97-377, December 18, 1982 (the first Act to include this repeal provision).
Provided further, That in addition to the amounts provided herein, $15,750,000 shall be available to the Health Resources and Services Administration from reimbursements from other Federal Agencies and Departments for the operation of employee occupational health programs under 5 U.S.C. 7901.	Provides authorization for depositing funds to this appropriation which are collected for the operation of employee occupational health programs in Federal agencies and departments.
Provided further, That during fiscal 1987, the Secretary of Health and Human Services shall enter into commitments totalling $100,000,000 to guarantee up to 80 per centum of the value of Health Education Assistance Loans under subpart I of part C of title VII of the Public Health Service Act, so long as the Student Loan Insurance Fund maintains a positive balance.	Provides a limit in the appropriations language on he level of new loans which may be guaranteed for up to 80 percent under the Health Professions Graduate Student Loan (HEAL) program.
Provided further, That the provisions of section 741(i) of he Public Health Service Act shall also apply to schools participating in the Nursing Student Loan program or lenders participating in the Health Education Assistance Loan program.	This provision allows lenders to charge borrowers life insurance fees on unpaid balances of guaranteed loans.

Provided further, That during the fiscal year, and within the resources and authority available under section 338 of the Public Health Services Act, gross obligations for the principal amount of direct loans under sections 335(c), 338(e)(1), and 338E of that Act shall not exceed $1,000,000.

This provision limits, for fiscal year 1986, the gross obligations for the principal amount of direct loans made by the National Health Service Corps loan programs as authorized by sections 335(c) (community site loans), 338C(e)(1) and 338E (private practice loans) of the PHS Act.

CENTERS FOR DISEASE CONTROL

Disease Control, Research, and Training

Language Analysis

Language Provision	Explanation
"...including insurance of official motor vehicles in foreign countries...".	No specific authorization exists for the provision regarding insurance; however, experience of the Centers for Disease Control in stationing Public Health Service officials overseas and at the Mexican Border indicates that this provision is essential. Unless adequate automobile insurance is provided, Public Health Service officials could be subject to arbitrary arrest if they were involved in an accident.
"...and hire, maintenance, and operation of aircraft...".	The Centers for Disease Control must maintain the ability to hire aircraft for testing of new insecticides and formulations and for applying the insecticides when outbreaks of mosquito-borne disease, such as encephalitis, occur in populous areas where no other method can be used to control the spread of the disease. Authority to purchase aircraft is no longer necessary and has been deleted.
"...[illegible] $[illegible] [illegible] [illegible] and [illegible] and renovation of [illegible] facilities..."	Repair and construction projects, require lead time for planning, engineering, and contracting procedures, which require longer than the fiscal year to complete and obligate, funds.
"...that [illegible] of [illegible] [illegible] or [illegible] to this appropriation for the [illegible] cost of such training..."	Provides specific authorization for depositing funds to this appropriation which are collected for training of health workers from private agencies, to offset the cost of the training program.

Language Provision	Explanation
"...that collections from user fees, including collections from training and reimbursements and advances for the full cost of proficiency testing of private clinical laboratories, may be credited to this appropriation."	Provides specific authorization to allow charging for the full cost of proficiency testing of private clinical laboratories and to allow all funds collected as user fees to be deposited to this appropriation.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH CARE FINANCING ADMINISTRATION

Identification of Appropriation Language Provisions, Earmarks, etc., Which Modify or Go Beyond Authorizing Legislation

Grants to States for Medicaid

Language Provision	Explanation
Provided, That no such State shall be entitled to payment for medical assistance costs incurred in fiscal year 1987 in excess of 109 per centum of the total amount the State expended for medical assistance under its State plan during fiscal year 1985 as determined on the basis of actual expenditure reports received by the Secretary as of January 31, 1986 and approved by the Secretary as of the start of fiscal year 1987.	This section establishes a cap on total Federal reimbursement to States for medical assistance and provides that individual State grants will be allocated in proportion to the relative share of each State's expenditures for fiscal year 1985.
For making payments to States (other than Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, and American Samoa) in cases of hardship, as determined under regulations of the Secretary, notwithstanding the 109 per centum limit described in the paragraph above, $300,000,000 which is the maximum amount the Secretary may obligate for these purposes.	This section provides for a one-time hardship pool to facilitate the States' transition to a capped program.
For making payments to States (other than Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, and American Samoa) for administrative and training expenses for fiscal year 1987, $756,838,000: Provided, That no funds may be paid from this or any other appropriation to a State to reimburse expenditures incurred after October 1, 1986 under Section 1903(a)(2), (3), (5), and (6) of the Social Security Act: Provided further, that notwithstanding title XIX of the Social Security Act, any use of funds appropriated under this Act by a State shall constitute that State's agreement to claim all future reimbursement for administrative costs under section 1903(a)(7) of the Act.	These provisions limit matching rates for State administration and training costs to no more than 50 per centum.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH CARE FINANCING ADMINISTRATION

Identification of Appropriation Language Provisions, Earmarks, etc., Which Modify or Go Beyond Authorizing Legislation

Grants to States for Medicaid

Language Provision	Explanation
Provided further, That in the case of any State (other than Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, and American Samoa) in which the ratio of total amounts of such administrative expenditures under its Medicaid State plan for FY 1987 to the average monthly number of individuals receiving benefits under its State plan in that fiscal year (called "per recipient administrative costs") exceeds 175 per centum of the national median of all such ratios (such ratios being established by the Secretary of Health and Human Services on the basis of the best data available when the amount payable under Section 1903 is determined, with subsequent adjustments made as necessary), no more than 25 per centum of the State's costs in excess of 175 per centum of the national median of such per recipient administrative costs may be included in the amount payable from this or any other appropriation.	This section provides that a State's "per recipient" administrative costs in excess of 175 percent of the median for such costs will be Federally matched at 25 per cent rather than 50 percent.
Provided, That the maximum amount available for medical assistance expenditures to a State for the first quarter of fiscal year 1988 shall not exceed the State's first quarter grant award for fiscal year 1987, increased or decreased by a percentage estimated by the Secretary to be equal to the projected percentage increase or decrease (as the case may be) in the index of the medical care expenditure category of the Consumer Price Index for all urban consumers (U.S. City average) for the 12-month period ending September 30, 1988.	This section provides that each State's first quarter grant for medical assistance payments for FY 1988 may not exceed its first quarter grant award for FY 1987, as adjusted for inflation.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH CARE FINANCING ADMINISTRATION

Identification of Appropriation Language Provisions, Earmarks, etc., Which Modify or Go Beyond Authorizing Legislation

Grants to States for Medicaid

Language Provision	Explanation
For making payments to States (other than Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, and American Samoa) for administrative and training expenses for the first quarter of fiscal year 1988, and subject to the same limitations as apply to amounts appropriated herein for the current fiscal year, $337,700,000.	This section provides that administrative expenses for the first quarter for FY 1988 are governed by the same funding restrictions as those for FY 1987, i.e., a single matching rate of 50 percent and a threshold on per recipient administrative costs.
During the eighteen-month period beginning with the first month in which a refugee enters the United States, a refugee to whom cash or medical assistance is available under section 412(e) of the Immigration and Nationality Act shall be ineligible for assistance under title IV-A and XIX of the Social Security Act.	This section provides that Federal reimbursement under Medicaid will not be available for refugees who are already eligible for cash or medical assistance under the Immigration and Nationality Act administered by the Office of Refugee Resettlement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH CARE FINANCING ADMINISTRATION

Identification of Appropriation Language Provisions, Earmarks, etc., Which Modify or Go Beyond Authorizing Legislation

Program Management

Language	Explanation
. . . together with not to exceed $1,163,944,000 to be transferred to this appropriation as authorized by Section 201 (g) of the Social Security Act, from the Federal Hospital Insurance and the Federal Supplementary Medical Insurance Trust Funds referred to therein . . .	Authorizing legislation provides for payments of administrative costs related to Title XVIII programs. This provision permits the transfer of such trust fund monies to this account to provide allocations of costs between trust funds and general funds.
Provided, That in addition $50,000,000 shall similarly be derived by transfer from said trust funds and shall be expended only to the extent necessary to process workloads not anticipated in the budget estimates or to meet unanticipated costs of agencies or organizations with which agreements have been made to participate in the administration of Title XVIII and after maximum absorption of such costs within the remainder of the existing limitation has been achieved.	This provision provided the authority to tranfers additional amounts from the trust funds for for contractory costs associated with workload that was not anticipated in the budget. These transfers may not exceed $50,000,000.
Provided further, that no funds shall be available for obligation under Section 1842(g) of the Social Security Act.	Section 1842(g) of the Social Security Act requires the Railroad Retirement Board (RRB) to contract with a carrier or carriers to process claims for RRB beneficiaries. This provision would prohibit obligation of funds for a separate RRB contractor. Claims would be processed by the regular Medicare contractors.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH CARE FINANCING ADMINISTRATION

Identification of Appropriation Language Provisions, Earmarks, etc., Which Modify or Go Beyond Authorizing Legislation

Program Management

Language	Explanation
Provided further, That no funds shall be available for obligation to a fiscal intermediary under section 1816 of the Social Security Act unless the fiscal intermediary has been selected by the Secretary of Health and Human Services without regard to any nomination procedures.	Currently, providers may nominate the intermediary that would pay their claims. This provision would eliminate the provider nomination process and assign providers to intermediaries without regard to their preferences.
Provided further, That funds shall be available for agreements or contracts with fiscal intermediaries or carriers under sections 1816(c) and 1842(b) of the Social Security Act on a basis other than the cost of such agreements or contracts.	This provision would provide the authority to use contracting procedures other than the current cost reimbursement contracting.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SOCIAL SECURITY ADMINISTRATION

Identification of Appropriation Language Provisions, Earmarks, etc., Which Modify or Go Beyond Authorizing Legislation

Language Provison in the Limitation on Administrative Expenses Account	Explanation
Provided that travel expenses payments under section 1631(h) of such Act may be made only when travel of more than seventy-five miles is required.	The Social Security Disability Amendments of 1980 enacted into substantive law the requirement to pay for travel incident to medical examinations and for claimants, their representatives and witnesses to attend reconsideration interviews and hearings for SSI claims. This provision restores the mileage limitation which was established in SSI regulations before enactment of the 1980 disability amendments and makes travel reimbursement policy the same for SSI and Social Security claimants.
"For necessary expenses not more than $4,011,373,000 may be expended.	This earmark language first introduced in the 1982 Supplemental Appropriations Act (P.L. 97-257) makes available, until expended, funds for automated data processing (ADP) and telecommunications leases, purchases or contracts for the purposes of modernizing SSA's systems. It protects against the unpredictability of timing in major systems purchases and telecommunications acquisitions that are particularly prone to procurement challenges which can delay final procurement into the next fiscal year.

Language Provision in the Limitation on Administrative Expenses Account	Explanation
"...Provided further, That none of the funds appropriated by this Act may be used for the manufacture, printing, or procuring of social security cards...where paper and other materials used in the manufacture of such cards are produced, manufactured, or assembled outside of the United States".	This provision bars funding of certain functions related to printing social security cards in order to encourage use of domestic printing and manufacturing resources for this activity.
Language Provision in the Special Benefits for Disabled Coal Miners Account	
...including the payment of travel expenses on an actual cost or commuted basis, to an individual, for travel incident to medical examinations, and to parties, their representatives and all reasonably necessary witnesses for travel within the United States, Puerto Rico and the Virgin Islands, to reconsideration interviews and to proceedings before administrative law judges.	This language authorizes payment for travel incident to medical examinations, reconsiderations, and hearings. This was provided because it is sometimes necessary to request applicants to travel long distances for the convenience of the government in the adjudication of an application claim.

Department of Health and Human Services
Office of Refugee Resettlement
Identification of Appropriation Language Provisions, Earmarks, etc.,
Which Modify or Go Beyond Authorizing Legislation

Language Provision	Explanation
"... Provided, That during the eighteen-month period beginning with the first month in which a refugee enters the United States, such refugee shall be deemed ineligible for assistance under title IV or XIX of the Social Security Act for any month in such period for which cash or medical assistance is available under section 412(e) of the Immigration and Nationality Act:..."	The 1987 budget request proposes a new policy that refugees be eligible only for special Refugee Cash and Medical Assistance benefits under this appropriation (rather than AFDC and Medicaid benefits) for the first eighteen months in the U.S. Where refugees would otherwise be eligible for categorical assistance, benefits under the refugee program will at least equal the level of comparable categorical benefits.
"... Provided further, That such funds may be expended for individuals who would meet the definition of "Cuban and Haitian entrant" under Section 501(e) of the Refugee Education Assistance Act, but for the application of paragraph (2) (B) thereof"	This language authorizes the Department of Health and Human Services to reimburse States for assistance authorized by Title V of the Refugee Education Assistance Act for Cuban and Haitian Entrants. This applies to entrants with legally enforceable orders of exclusion or deportation only when removal has not been practicable.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Community Services

Identification of Appropriation Language Provisions, Earmarks, etc., Which Modify or Go Beyond Authorizing Legislation

Language Provision	Explanation
For carrying out the the Community Services Block Grant Act, $372,435,000, of which $19,920,000 shall be for carrying out section 681(a)(2)(A), $4,050,000 shall be for carrying out section 681(a)(2)(D), $3,035,000 shall be for carrying out section 681(a)(2)(F). (Department of Health and Human Services Appropriation Act, 1986.)	The Department has submitted a legislative proposal to repeal the Community Services Block Grant Act and the Community Development Act of 1981.
Provided further, That notwithstanding any other provision of this Act, amounts otherwise provided by this Act for the following accounts and activities are reduced by the following amounts:	
OFFICE OF COMMUNITY SERVICES	
"Community services block grant, discretionary funds", $2,135,000 of which $1,570,000 applies to section 681(a)(2)(A), $330,000 applies to section 681(a)(2)(D), and $235,000 applies to section 681(a)(2)(E); (Department of Labor, Health and Human Services and Education and Related Agencies Appropriation Act, 1986.)	

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Total Budget Authority
Fiscal Years 1967 through 1987
(In thousands of dollars)

	1967	1968	1969	1970	1971	1972	1973	1974
Department of Health and Human Services—Summary:								
Total BA	9,419,505	11,197,333	46,410,125	55,698,445	61,986,918	72,214,960	83,885,122	96,016,743
General Funds	5,048,041	5,941,740	8,102,698	12,087,958	14,560,822	20,242,014	23,046,140	22,894,398
Trust Funds	4,371,464	5,255,593	38,307,427	43,610,487	47,426,096	51,972,946	60,838,982	73,122,345

	1975	1976	1977	1978	1979	1980	1981	1982
Department of Health and Human Services—Summary:								
Total BA	111,408,102	122,050,532	140,184,510	154,205,068	173,638,512	199,533,340	256,394,821	248,208,697
General Funds	27,828,062	32,843,593	35,599,405	37,021,820	39,800,290	54,372,509	61,257,147	63,169,734
Trust Funds	83,580,040	89,206,939	104,585,105	117,183,248	133,838,222	145,160,831	195,137,674	185,038,963

	1983	1984	1985	1986 1/			1987 1/
				(Appropriated)	(After Sequestering)	(Current Request)	
Department of Health and Human Services—Summary:							
Total BA	286,008,669	256,186,351	281,930,761	284,242,437	283,371,625	283,117,637	312,816,403
General Funds	68,554,078	74,570,931	81,979,443	78,724,342	77,931,590	77,793,481	82,588,744
Trust Funds	217,454,591	181,615,420	199,951,318	205,518,095	205,440,035	205,324,156	230,227,659

1/ Estimates based on 1987 President's Budget.

T-13

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Total Expenditures
Fiscal Years 1967 through 1987
(In thousands of dollars)

	1967	1968	1969	1970	1971	1972	1973	1974
Department of Health and Human Services-Summary:								
Total Expenditures	7,605,243	10,682,982	44,055,885	49,604,658	58,016,721	68,277,687	79,017,623	89,627,371
General Funds	4,194,587	5,350,721	10,154,518	12,181,163	14,268,013	19,301,016	20,448,418	22,412,537
Trust Funds	3,410,656	5,332,261	33,901,367	37,423,495	43,748,708	48,976,671	58,569,205	67,214,834

	1975	1976	1977	1978	1979	1980	1981	1982
Department of Health and Human Services-Summary:								
Total Expenditures	107,183,885	123,215,505	142,056,251	152,340,545	172,801,675	198,426,959	[illegible]5,857,541	254,911,746
General Funds	27,744,096	31,534,240	34,780,008	33,302,508	39,624,717	52,636,868	60,335,410	50,328,734
Trust Funds	79,439,789	91,681,265	107,276,343	119,038,037	133,176,958	145,790,091	195,522,131	204,583,012

	1983	1984	1985	1986			1987
				(Appropriated)	(After Sequestering)	(Current Request)	
Department of Health and Human Services-Summary:							
Total Expenditures	281,335,445	249,550,717	266,095,607	270,753,747	271,153,640	280,523,590	293,516,090
General Funds	72,397,104	52,634,056	76,650,766	69,887,692	70,375,762	79,745,712	80,571,795
Trust Funds	208,938,341	196,916,661	189,444,841	200,866,055	200,777,878	200,777,878	212,944,295

1/ Estimates based on 1987 President's Budget.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

I-14

Summary
Fiscal Years 1977 through 1983
Authorization versus Appropriation
(In Thousands of Dollars)

	1977	1978	1979	1980	1981	1982	1983
LABOROR-HHS COMMITTEE Total Definite Authorization							
Public Health Service:							
Health Resources and Services Administration:							
Health Resources and Services	---		---		---	$2,383,300	$1,979,550
Health Services	$2,159,[illegible]	1,120,424	562,864	$1,[illegible],169	$1,146,426	---	---
Health Resources Administration	1,713,123	1,300,492	[illegible],036	365,624	355,000	---	---
Centers for Disease Control	96,100	105,000	52,000	299,500	431,000 1/	169,500 2/	88,500
National Institutes of Health	1,759,000	1,747,245	46,485	1,877,300	1,974,200	2,037,800	195,000
Alcohol, Drug Abuse, and Mental Health Administration	416,750	[illegible]	215,500	215,500	253,500	774,500	707,500
Assistant Secretary for Health	---	123,200	96,005	101,000	112,500	93,000	100,760
Subtotal, PHS (Labor-HHS)	4,856,081	4,915,159	1,707,050	5,752,093	4,992,626	5,458,100	3,071,310
Health Resources and Services Administration: Indian Health Service	---	7,850	9,000	234,985	99,185 5/	114,795 5/	131,445 5/
Total, PHS	4,856,081	4,923,009	1,716,050	5,987,078	5,091,811	5,572,895	7,202,255
Health Care Financing Administration	---	2,518	2,518	2,518	2,518	2,518	1,718
Social Security Administration	---		---	---	---	---	1,875,000
Office of Refugee Resettlement	---	---	---	200,000	200,000	200,000	114,000
Human Development Service	1,698	5,818	2,171	4,133,000	4,173,100	2,691,000	5,202,694
Office of Community Services	---	---	---	---	---	389,375	389,375
Total, HHS (Labor-HHS)	4,857,759	4,919,495	1,711,229	10,127,611	9,568,244	8,740,993	10,654,097
Total, HHS	$4,857,759	$4,927,345	$1,721,539	$10,362,596	$9,667,429	$8,855,788	$10,785,542

1/ Includes authorization of Health Incentive Grants (Section 314(d) in the amount of $170,000.

2/ Includes unfunded authorization for Tuberculosis Grants of $9,000 (Section 317(j)(2)) and Prevention Formula Grants of $75,000 (Section 315(k)(z)).

DEPARTMENT OF HEALTH AND HUMAN SERVICES T-14

Summary

Fiscal Years 1984 through 1987 Authorization Versus Appropriation

(In Thousands of Dollars)

	1984	1985	1986 Appropriation	1986 After Sequestering	1986 Current Request	1987
Total Appropriations Against Ceiling Authorization						
Public Health Service:						
Health Resources and Services Administration						
Health Resources and Services	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	$ 478,000
Health Services						---
Health Resources Administration						---
Centers for Disease Control	[illegible]	[illegible]	[illegible]	[illegible]	176,881	182,176
National Institutes of Health	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	2,149,390
Alcohol, Drug Abuse, and Mental Health Administration	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	508,529
Assistant Secretary for Health	[illegible]	[illegible]	[illegible]	[illegible]	55,788	61,941
Subtotal, PHS (Labor-HHS)	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	3,382,036
Health Resources and Services Administration						
Indian Health Services	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	3/
Total, PHS	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	3,382,036
Health Care Financing Administration				---	---	---
Social Security Administration	[illegible]	[illegible]	[illegible]	2,009,708	2,009,700	2,100,000
Office of Refugee Resettlement	4/	4/	4/	--- 4/	--- 4/	--- 4/
Human Development Services	[illegible]	[illegible]	[illegible]	1,620,743	1,796,951	762,100
Office of Community Services	[illegible]	[illegible]	[illegible]	354,117	172,139	3,612
Total, HHS (Labor-HHS)	[illegible]	[illegible]	8,047,304	7,662,159	7,304,440	6,247,748
Total, HHS	[illegible]	[illegible]	$8,047,304	$7,662,159	$7,304,440	$6,247,748

2/ Appropriation was a Continuing Resolution.

3/ The proposed "Indian Health Care Amendments of 1985" which would extend and amend the Indian Health Care Improvement Act has not been enacted.

4/ The Refugee Act of 1980, as amended, expired as of September 30, 1983. Congress has not enacted re-authorization legislation. Since FY 1984, the program has been operating under authority of various Continuing Resolutions.

DEPARTMENT OF HEALTH AND HUMAN SERVICES T-14
Summary
Fiscal Years 1977 through 1983
Authorization versus Appropriation
(In Thousands of Dollars)

Total Appropriations Against Define Authorization	1977	1978	1979	1980	1981	1982	1983
Public Health Service:							
Health Resources and Services Administration:							
Health Resources and Services	---		---	---	---	$1,589,098	$1,345,841
Health Services	$ 886,266	1/	558,844	$1,201,948	$1,077,344	---	---
Health Resources Administration	282,450	1/	315,041	415,352	122,892	---	---
Centers for Disease Control	82,500	1/	25,[illegible]	112,282	120,382	63,236	72,428
National Institutes of Health	1,173,722	1/	12,421	1,749,640	--- 2/	--- 2/	--- 2/
Alcohol, Drug Abuse, and Mental Health Administration	909,0[illegible]	1/	413,589	414,192	331,788	517,767	485,337
Assistant Secretary for Health			36,[illegible]	147,184	172,944	54,507	60,052
Subtotal, PHS (Labor-HHS)	3,258,001	[illegible]	1,106,968	3,396,401	2,025,350	2,220,608	1,963,658
Health Resources and Services Administration:							
Indian Health Service	---	---	6,788	79,153	92,326	55,477	85,617
Total, PHS	3,258,001	---	1,113,756	3,475,554	2,118,676	2,276,085	2,049,275
Health Care Financing Administration	---	---	---	---	---	---	---
Social Security Administration	---	---	---	---	---	---	1,975,000
Office of Refugee Resettlement	---	---	---	144,492	151,148	106,062	76,100
Human Development Services	1,902	1,398	1,478	3,648,985	3,254,319	2,631,000	4,940,399
Office of Community Services	---	---	---	---	---	365,817	384,086
Total, HHS (Labor-HHS)	3,259,903	1,398	1,108,446	7,189,880	5,432,817	5,323,487	9,339,243
Total, HHS	$3,259,903	$1,398	$1,115,234	$7,269,031	$5,525,542	$5,378,964	$9,424,860

1/ No funds were appropriated in fiscal year 1978; agencies were funded under continuing resolution.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Total Employment
Fiscal Years 1967 through 1987

	1967	1968	1969	1970	1971	1972	1973
Department of Health Human Services-Summary:							
Total authorized positions FTP..........	91,834	104,004	98,427	95,341	[illegible]	100,579	112,614
Total, end-of-year employment, FTP.......	91,268	102,349	96,503	91,818	95,579	97,517	107,105
Total, FTE * employment...............	96,740	102,247	102,443	99,900	100,608	100,698	109,647

	1974	1975[1]	1976	1977	1978	1979	1980
Department of Health and Human Services-Summary:							
Total authorized positions FTP..........	[illegible]	[illegible]	130,628	135,575	142,237	147,209	145,106
Total, end-of-year employment, FTP........	116,591	127,543	128,691	131,242	139,121	138,345	136,582
Total, FTE * employment...............	127,009	140,271	143,552	143,071	152,579	157,933	158,239

	1981	1982	1983	1984	1985	1986	1987
Department of Health and Human Services-Summary:							
Total authorized positions, FTP..........	145,703	136,192	130,857	135,431	129,833	125,889	121,648
Total, end-of-year employment, FTP........	131,554	125,348	125,568	121,308	117,619	122,450	117,845
Total, FTE * employment..............	148,486	141,548	141,715	136,969	131,243	127,367	122,873

*Work years shown prior to FY 1981.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUMMARY

Appropriations for Which Funds Lapsed in FY 1985

Appropriation	FY 1985 Lapsed Funds
Public Health Service:	
Health Resources and Services Administration:	
Health Resources and Services	$ 5,235,000
Centers for Disease Control	58,000
National Institutes of Health	3,012,000
Alcohol Drug Abuse, and Mental Health Administration	1,574,000
Assistant Secretary for Health	558,000
Subtotal, PHS (Labor-HHS)	10,437,000
Food and Drug Administration	334,000
Health Resources and Services Administration	
Indian Health Services	811,222
Total, PHS	11,582,222
Health Care Financing Administration	12,058,000
Social Security Administration	170,514,000
Office of Refugee Resettlement	9,689,000
Human Development Services	4,951,000
Office of Community Services	189,744
Departmental Management	1,837,000
Subtotal, HHS (Labor-HHS)	209,675,744
Office of Consumer Affairs	1,000
Total, HHS	$ 210,821,966

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Travel by Appropriations, FY 1985-1987
(In thousands of dollars)

Appropriation	Fiscal Years 1985	1986	1987
Public Health Service:			
Health Resources and Services Administration: Health Resources and Services Administration	[illegible]	$ 5,502	$ 3,677
Centers for Disease Control	[illegible]	6,496	5,784
National Institutes of Health	[illegible]	17,229	17,429
Alcohol, Drug Abuse, and Mental Health Administration	[illegible]	[illegible]	1,181
Saint Elizabeths Hospital	[illegible]	172	177
Assistant Secretary for Health	[illegible]	[illegible]	2,701
Subtotal, PHS (Labor-HHS)	[illegible]	[illegible]	[illegible]
Food and Drug Administration	[illegible]	[illegible]	[illegible]
Health Services Administration: Indian Health Service	[illegible]	[illegible]	[illegible]
Total, PHS	[illegible]	[illegible]	[illegible]
Health Care Financing Administration	[illegible]	[illegible]	[illegible]
Social Security Administration	[illegible]	[illegible]	[illegible]
Office of [illegible]	[illegible]	[illegible]	[illegible]
Office of [illegible]	[illegible]	[illegible]	[illegible]
Human Development Services	[illegible]	[illegible]	[illegible]
Office of Community Services	[illegible]	[illegible]	[illegible]
Departmental Management	[illegible]	[illegible]	[illegible]
Subtotal, HHS, (Labor-HHS)	[illegible]	[illegible]	[illegible]
Office of Consumer Affairs	41	[illegible]	41
Total, HHS	[illegible]	[illegible]	[illegible]

ACQUIRED IMMUNODEFICIENCY SYNDROME
Obligations

Public Health Service:	1983 Actual	1984 Actual	1985 Actual	1986 Approp.	1986 Available After Sequestering	1986 Revised	1987 Estimate 1/
National Institutes of Health:							
National Cancer Institute............	$9,790,000	$16,827,000	$26,874,000	$28,442,000	$27,218,000	$27,218,000	--- ($47,151,000)
National Heart, Lung, and Blood Institute..	1,202,000	4,871,000	9,323,000	11,200,000	10,718,000	10,718,000	--- (17,091,000)
National Institute of Dental Research......	25,000	91,000	97,000	684,000	655,000	655,000	--- (2,733,000)
National Institute of Neurological and Communicative Disorders & Stroke...	684,000	1,510,000	1,168,000	1,500,000	1,435,000	1,435,000	--- (1,575,000)
National Institute of Allergy and Infectious Diseases..	9,223,000	19,616,000	23,273,000	27,067,000	25,903,000	25,903,000	--- (67,520,000)
National Institute of Child Health and Human Development....	---	---	---	---	---	---	--- (674,000)
National Eye Institute.	45,000	60,000	200,000	100,000	96,000	96,000	--- (104,000)

	1983 Actual	1984 Actual	1985 Actual	1986 Approp.	1986 Available After Sequestering	1986 Revised	1987 Estimate 1/
National Institutes of Health (continued):							
Division of Research Resources..............	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	--- ([illegible])
Office of the Director	---	---	---	[illegible]	[illegible]	[illegible]	---
Total, NIH............	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	--- ([illegible])
Food and Drug Administration..........	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	9,765,000
Centers for Disease Control..................	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	--- (45,509,000)
Alcohol, Drug Abuse, and Mental Health Administration..........	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	12,158,000	--- (13,733,000)
Health Resources and Services Administration..........	---	---	---	38,000,000	36,412,000	---	---
Office of the Assistant Secretary for Health...	---	---	---	---	---	---	203,482,000
TOTAL, PHS............	28,736,000	61,460,000	108,618,000	244,307,000	233,802,000	192,727,000	213,247,000

1/ The amounts in parentheses are proposed to be appropriated to the Office of the Assistant Secretary for Health and reimbursed to the agencies.

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

Major program initiatives were undertaken this year to expedite the discovery, development, and testing of drugs against AIDS, and particularly to involve the extramural scientific/medical community and additional AIDS patients in these efforts. In a joint project undertaken by NCI and NIAID, drugs are being screened for their antiviral properties using an NCI-developed assay. So far, several hundred candidate compounds have been tested, and seven are in the early phases of clinical evaluation at NIH and elsewhere. An AIDS Drug Selection Committee has been established by NIAID and NCI to coordinate the development and testing of candidate drugs. This committee will direct efforts to review scientific data of candidate compounds and make appropriate recommendations with regard to their use in clinical trials.

In order to expand treatment and treatment-related studies around the country, the NCI and NIAID issued a solicitation in December 1985 requesting applications for funding National Cooperative Drug Discovery Groups. The resulting awards will be aimed at the preclinical discovery of effective agents to interfere with virus replication or function and to restore or maintain immune responses. The NIAID has also issued a joint solicitation for the establishment of AIDS Treatment Evaluation Units. These units will support phase I and II clinical trials of antivirals, immune modulators, and antibiotics in patients with AIDS and ARC.

To speed information about new therapeutic agents to researchers and physicians treating AIDS patients, the NCI recently added data on AIDS treatment protocols to the Physician Data Query (PDQ) system. When fully operational, the system will give physicians around the country access--through personal computers or word processors with telephone hookups--to information on the most promising AIDS therapies, locations of experimental treatment projects, and the names of AIDS specialists.

National Cancer Institute

In FY 1986, NCI made important contributions in many areas of AIDS research. These included advances in understanding the molecular biology of human T-cell lymphotropic virus-III (HTLV-III), the causative agent of AIDS, as well as developing a vaccine [illegible] for the [illegible] in understanding the natural history and transmission of AIDS, and in identifying potential new therapies for the disease.

[illegible]

[illegible]

[illegible] Dr. Mark [illegible] Dr. Takis [illegible]

[illegible] HTLV-III can [illegible] that are [illegible] the virus [illegible] This research was conducted by Dr. [illegible] Fisher and colleagues.

Scientists also learned that the HTLV family* of retroviruses possesses a unique strategy for usurping the host cell's cellular machinery. This represents an entirely new type of regulatory mechanism for activating cells to produce more virus. The retroviruses produce a protein from a gene, called the tat gene, that turns on viral genes and possibly normal cellular genes at widely distant sites in the chromosomes of an infected cell. This phenomenon is called trans-acting transcription (tat) regulation. Identification of the tat gene of HTLV-III and its unique splicing mechanism was made by NCI intramural scientist Dr. Suresh Arya and colleagues.

In related research, NCI-funded investigator Dr. William Haseltine and colleagues at the Dana-Farber Cancer Institute and Harvard Medical School have shown that bovine leukemia virus (BLV), a retrovirus that causes leukemia in cattle, has the tat gene. They also found that HTLV-III expresses tat activation at a very high level. This may account at least in part for HTLV-III's virulent "cell-killing" activity, in contrast to the abnormal cell proliferation that occurs with HTLV-I and -II. However, whether tat is an essential part of HTLV-III's cell-killing activity is not yet determined.

In other research supported by NCI, Dr. [illegible] and colleagues at The Johns Hopkins University School of Medicine in Baltimore found that the tat gene was also found in the [illegible] lentiviruses, a family of retroviruses that infect various animals and causes chronic diseases. Taken together, these findings of a common tat gene in all these retroviruses (HTLV-I, -II, -III, BLV, and lentiviruses) suggest that these retroviruses may share a common ancestral [illegible].

Determining the family of retroviruses to which HTLV-III belongs and its relationship to other such retroviruses is important to understand how HTLV-III causes disease.

The genetic organization of HTLV-III shows greater similarity to the lentivirus family than to HTLV-I or -II, which suggests that HTLV-III may be a human lentivirus. Dr. Matthew A. Gonda of Program Resources, Inc., at NCI's Frederick Cancer Research Facility, found that HTLV-III and visna virus, a pathogenic lentivirus that causes a chronic degenerative neurologic disease in sheep, are structurally and genetically very similar. In fact, these two retroviruses are more closely related than HTLV-III is to HTLV-I or -II. HTLV-III causes neurological disease in AIDS patients, as does the visna virus in sheep. This research was done in collaboration with The Johns Hopkins University School of Medicine and the [illegible] Laboratory.

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* The family of retroviruses known as HTLV, human T-cell lymphotropic viruses, comprises HTLV-I, which is strongly associated with an adult form of leukemia-lymphoma; HTLV-II, which has not been linked to any disease; and HTLV-III, the cause of AIDS.

NCI intramural scientist Dr. Ing-Ming Chiu and colleagues found, by direct nucleic acid sequence comparisons, that HTLV-III also is similar in its genetic structure to the lentiviruses caprine (goat) arthritis encephalitis virus and equine infectious anemia virus. These and other similarities lend support to the belief that they might [illegible]. HTLV-III and the lentiviruses [illegible] and both infect [illegible] cells.

[illegible] HTLV-III may have originated in Africa. [illegible]

[illegible]

[illegible]

[illegible]

[illegible]

sity School of Public Health and colleagues, with NCI-funding, detected gp120 as well as gp160. Dr. Essex's research was done in collaboration with Harvard's Dana-Farber Cancer Center and NIAID intramural scientist Dr. John Coligan.

In another study, Dr. Essex found that gp160 and 120 are the major target antigens for antibodies from patients with AIDS, ARC, and some healthy homosexual men. This suggests that detection of antibodies specifically against these glycoproteins may serve as a confirmatory test for the presence or absence of antibodies to HTLV-III in human serum samples. This NCI-funded study was done in collaboration with New England Deaconess Hospital.

[illegible] tions, including gp120 and gp41, [illegible] protective immunity [illegible] with HTLV-III. Artificial [illegible] have been developed. [illegible] assays. [illegible]

[illegible]

[illegible]

[illegible]

Epidemiology

To determine the natural history of AIDS, NCI's Dr. James Goedert and colleagues are following prospectively five populations at high risk for AIDS. In these groups, from 4 to 20 percent of individuals infected with HTLV-III and followed for 32 months were diagnosed with AIDS. When the study began in 1982, the highest infection rate for HTLV-III, 54 percent, was seen among homosexual men from New York City. By mid-1985, 20 percent of those who were infected had developed AIDS, and an additional 25 percent had developed lesser clinical manifestations of immune deficiency. In the other groups, the proportion of those infected with HTLV-III and who subsequently developed AIDS was much lower: 10 percent of homosexual men in Washington, D.C.; 4 percent of IV drug abusers in New York City; 0 percent of homosexual men in Denmark; and 0 percent of hemophiliac patients in Pennsylvania. [illegible] that the higher rate of developing AIDS [illegible] the New York homosexual men most likely reflects the longer duration of infection in the New York group.

[illegible] study, one conducted by Dr. [illegible] of the Milton S. Hershey Medical Center of The Pennsylvania State University, [illegible] with Dr. Goedert. They [illegible] that all those infected with HTLV-III [illegible] lymphadenopathy (persistent-ly [illegible]). As [illegible] HTLV-III infection and manifestation of AIDS [illegible].

The [illegible] population-based tumor registries was used to monitor the occurrence of cancers that may be associated with the [illegible], a rare type of cancer that [illegible] in young [illegible] in AIDS patients, and [illegible] that [illegible] may be associated with the disorder. [illegible] homosexuality is not [illegible], Dr. Robert Biggar [illegible] NCI [illegible] 20 to 54 years old [illegible] and found a 50-fold increase in the incidence of Kaposi's sarcoma between 1973-1980 and [illegible] non-Hodgkin's lymphomas. These increases [illegible] AIDS patients. No increases were seen for other cancers [illegible], but it is possible that there may be a longer delay for development of other cancers, and they may appear in the future.

Because Kaposi's sarcoma has been endemic in some areas of Africa for years, Dr. [illegible] of the Institute of Tropical Medicine, [illegible], in collaboration with Dr. Biggar, studied the [illegible] of Kaposi's sarcoma in [illegible]. They concluded that in this [illegible] the classical form of the disease is not associated with HTLV-III infection in the general population.

Studying transmission of the virus, Dr. Goedert found that homosexual men from Washington, D.C., who had sexual contact with men from high-risk areas for AIDS had lower helper T-cell counts than Washington homosexuals who did not. A strong, consistent association was also seen between the number of sexual contacts with men from high-risk areas and the extent to which helper T cells were reduced. This suggests that frequent male homosexual contact with residents of areas where AIDS is common may be an important means of spread of the causal agent. Washington, D.C., was a relatively low-risk area for AIDS, but the risk has subsequently increased. The laboratory tests were performed under the direction of NCI intramural scientist Dr. Dean Mann, through a contract with the Uniformed Services University of Health Sciences, Bethesda.

Studies of health care workers and of household contacts of persons with HTLV-III infection demonstrated that this virus is seldom transmitted through non-sexual contacts, even when someone is stuck with a contaminated needle. In a study of 361 health care workers from medical institutions that care for AIDS patients, only three cases of HTLV-III infection were reported, all of whom were accidentally stuck with sharp instruments that were clearly or probably contaminated with the blood of AIDS patients. This research was conducted by Dr. Stanley Weiss and other NCI scientists in collaboration with the National Institute on Drug Abuse; Downstate Medical Center, Brooklyn; St. Luke's-Roosevelt Hospital Center, New York; and New England Deaconess Hospital, Boston.

Dr. Martin Hirsch and colleagues of the Massachusetts General Hospital studied 85 employees who had been stuck by infected needles or had repeated exposure to specimens from AIDS patients over a 3-year period. None of the hospital workers showed evidence of HTLV-III infection, according to preliminary findings. The Hirsch and Weiss studies suggest that isolation procedures currently recommended for AIDS are adequate and reaffirm the importance of following the Public Health Service's guidelines on general hospital and laboratory precautions for AIDS.

In two studies of members of households of hemophiliacs, Dr. Goedert, Dr. Mads Melbye of the Institute of Cancer Research and Blood Bank, Aarhus, Denmark, and colleagues found no evidence of infection among household members other than sexual partners of hemophiliacs who had been infected with HTLV-III.

In other research, Dr. Michael Marmor of New York University looked at cytomegalovirus (CMV), a type of herpesvirus, as a possible co-factor for development of Kaposi's sarcoma associated with AIDS. For unknown reasons, Kaposi's sarcoma associated with AIDS has been largely confined to homosexual men. CMV infection is prevalent among homosexual men and, therefore, is difficult to study in this group. Dr. Marmor found an association between frequency of CMV infection and Kaposi's sarcoma among three AIDS risk groups: frequency of CMV infection and Kaposi's sarcoma was

Cancer Group [illegible] patients. Interestingly, in [illegible], and [illegible]. Further study will be needed to clarify [illegible].

[illegible]

[illegible] HTLV-III, [illegible] and [illegible] effective against HTLV-III. An NCI [illegible] sensitivity [illegible] to test the efficacy of suramin [illegible] inhibit a viral enzyme [illegible] last year [illegible] *in vitro*.

[illegible] could be administered orally [illegible] activity against [illegible] at six [illegible] New York City; New England [illegible] University [illegible] University of [illegible].

[illegible] HTLV-III [illegible] HTLV-III infection [illegible] patients. He has [illegible] brain [illegible] treatment of [illegible] blood-brain barrier. This study was done with [illegible] intramural scientist Dr. [illegible] University Medical College in New York City, New [illegible] hospitals, and the University of Medicine and Dentistry of New Jersey, Newark.

Preliminary [illegible] studies at the NIH Clinical Center [illegible], have shown that this agent can be absorbed orally and that it does cross the blood-brain barrier. In addition, [illegible] patients who are now receiving [illegible] dose of the drug are showing evidence of improvement in the number and function of the T-cells that appear [illegible] by AIDS. [illegible], there also is an improvement of clinical status as measured by such factors as weight gain, [illegible] of fever and night sweats, and extent of [illegible]. It is [illegible] to draw any conclusions about safety or efficacy of this [illegible]. However, the results to date suggest that it might be appropriate to initiate wide-scale experimental therapy with the agent at several medical centers around the country to define what role, if any, the agent might have in the therapy of AIDS and its related conditions.

Azidothymidine was developed and provided to NCI by Burroughs Wellcome in Research Triangle Park, North Carolina. Dr. Broder's laboratory tested it *in vitro* using assays developed by NCI scientists and found it active against HTLV-III in February 1985. FDA approved it for use in patients in June 1985, and small pilot studies were then begun at the NIH Clinical Center and at Duke University. This demonstrates the cooperation that is taking place to find effective therapies for AIDS.

Other therapies are also being tested at the NIH Clinical Center under NCI and at several institutions around the country. These include anticancer drugs and immunorestorative agents such as interferon--a natural antiviral agent--and interleukin-2 (IL-2), a protein that plays a key role in immune response. However, no therapy has been discovered yet that completely corrects the underlying immune defect that characterizes AIDS.

To better define the extent of immunologic dysfunction seen in AIDS patients, NCI-funded investigator Dr. Charles Kirkpatrick of National Jewish Hospital and Research Center, Denver, found that AIDS patients with opportunistic infections and those with both opportunistic infections and Kaposi's sarcoma failed to produce IL-2. However, AIDS patients who had only Kaposi's sarcoma produced IL-2. Because IL-2 mediates production of interferon, inability to produce IL-2 could be an additional defect that predisposes AIDS patients to opportunistic infections. Although preliminary results of therapy for AIDS with IL-2 have not been encouraging, Dr. Kirkpatrick suggests that measurement of IL-2 may be important for selecting patient subgroups for treatment with it.

National Heart, Lung, and Blood Institute

The understanding that those who receive transfusions of blood, blood components or blood products are among the risk groups for contracting AIDS has led NHLBI to support a number of studies pertaining to transfusion-related AIDS.

Prior to the development of a suitable test to detect the antibody to HTLV-III in donated blood, the NHLBI supported a contract to collect and store serum specimens from blood donors in four major blood centers in the United States. Blood from these donors was transfused as whole blood or blood components and the corresponding serum specimens were frozen until the test to detect the HTLV-III antibody was licensed and available. The frozen specimens currently are being tested for antibody to HTLV-III. Donors with the antibody and recipients of their blood will be contacted and asked to participate in a larger prospective study. Its objective is to determine the natural history of HTLV-III infection among the blood donors and the recipients. More than 200,000 donors from whom serum specimens were collected have agreed to be tested and contacted for further evaluation.

In a limited study of transfusion-associated AIDS, NHLBI-supported investigators have identified 43 individuals who had donated blood since 1979 and subsequently developed AIDS. Blood or its components from these individuals were transfused into 211 recipients. Of these, 111 died of their original illness or an unrelated illness, 67 others are known to be alive and 33 have yet to be located. Seven cases of AIDS have been found among the recipients, and three have died of AIDS.

Data from 18 recipients tested for lymphadenopathy-associated virus (LAV), a virus essentially identical to HTLV-III, revealed that most recipients became positive for antibody to LAV if their blood donor developed AIDS within 1 year of donation. About half the recipients became antibody positive if the donor developed AIDS within 1 to 4 years of donation, and none of the recipients developed LAV antibody if the donor developed AIDS four years after donation. These findings indicate that the risk of LAV infection among blood recipients decreases as the time increases between blood donation and the development of AIDS in the donor.

In another donor/recipient study being conducted under NHLBI auspices by the Irwin Memorial Blood Bank in San Francisco 13 transfusion-associated cases of AIDS have been identified. Of these, six received blood from donors who remain healthy, four received blood from individuals who later developed AIDS and three remain under investigation.

The NHLBI continues to support research projects on the development of simpler, more rapid and sensitive assays than the ones currently in use to detect antibody to HTLV-III in blood. Furthermore, the Institute is supporting investigations in which recombinant DNA techniques are being evaluated as potential assays to detect HTLV-III.

Clearly, the ability to detect the presence of HTLV-III or its virus in donated blood is critical to the safety of the nation's blood resource. For those who are undergoing surgery and especially for those who receive periodic infusions of blood or its components, success in these research efforts is of paramount importance.

The American people must be assured of the safety of the nation's blood resources. That the 12 million blood transfusions and millions of infusions of blood components carried out each year resulted in so few adverse reactions is a testimony to the current technology. Research efforts now underway will further enhance the safety of this already safe system.

National Institute of Dental Research

At the NIDR, intramural scientists are studying AIDS because patients with this disease often develop severe oral infections and because the incidence of oral cancer in AIDS patients is high. In fact, oral viral or fungal infections of Kaposi's sarcoma lesions are frequently the first manifestation of AIDS in a patient.

Early studies showed that lymphocytes, which play a key role in the body's defense system, are suppressed in AIDS patients. In FY 1985, Drs. Phillip Smith and Sharon Wahl in NIDR's intramural program identified another defective cell in the immune system of AIDS patients--the monocyte. Monocytes are blood cells that engulf and kill foreign organisms and that switch on lymphocytes, which in turn activate an immune response. Drs. Smith and Wahl showed that monocytes do not function properly in AIDS patients: the cells produce neither enough of the chemicals that destroy bacteria nor sufficient amounts of the factor that activates lymphocytes. The failure of monocytes to provide proper defense against foreign organisms in AIDS patients contributes to the recurrent infections and unrestricted growth of tumors often seen in these patients. Such infections and tumors can be fatal.

Restoring monocyte function, then, would be expected to benefit AIDS patients. Drs. Smith and Wahl are now investigating drugs that may enhance the ability of monocytes to combat infections and tumor cells. Gamma interferon, for example, can activate monocytes to increase their potential for killing microorganisms. Colony-stimulating factor--a substance produced by activated immune cells--has been shown to induce proliferation and differentiation of immature monocytes. These and other drugs have a positive influence on monocytes and may have antiviral properties as well.

Recent evidence suggests that monocytes themselves may be one of the targets of infection by HTLV-III. If this is true, then monocytes may serve as a reservoir for the virus while simultaneously inhibiting the host's resistance to infection. Drs. Smith and Wahl have initiated several studies to address this issue, including: monitoring monocyte-killing capacity in AIDS patients receiving antiviral therapy. (These clinical trials are being carried out in collaboration with NIAID.)

Cytomegalovirus (CMV) is a common pathogenic virus associated with AIDS. Monocytes infected with CMV exhibit altered functional capacity similar to that observed in monocytes isolated from AIDS patients. Drs. Smith and Wahl were the first to show that CMV causes life-threatening enteritis and colitis in AIDS patients. Use of the new drug DHPG, which suppresses CMV replication, is effective in controlling the gastrointestinal manifestations of CMV seen in several AIDS patients. Studies in collaboration with NIAID are now under way to determine how CMV infects and influences monocytes. Such studies are important in understanding how viruses can suppress the immune system.

National Institute of Neurological and Communicative Disorders and Stroke

Intramural scientists at the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) are gaining a clearer understanding of the neurological complications of AIDS and are widening their search for an animal model for the disease.

Led by Nobel Laureate Dr. Carleton Gajdusek and Dr. Clarence Gibbs, Jr., an intramural research team this year confirmed reports by other investigators that approximately 45 percent of AIDS patients develop AIDS encephalopathy, a noninflammatory destruction of brain tissue that results in dementia. The NINCDS scientists found that this brain disease is caused by the AIDS virus.

Drs. Gajdusek and Gibbs also found that AIDS encephalopathy occurs more frequently in children than in adults. They are collaborating with scientists at the University of Medicine and Dentistry of New Jersey in Newark to determine why children's brains appear more susceptible to the AIDS virus.

In related work, these same investigators are studying how infected mothers transmit the AIDS virus to their developing babies

The first evidence of early neurological complications associated with the AIDS virus was found this year by NINCDS intramural investigator Dr. Sidney Houff. He evaluated a patient who 6 weeks after exposure to the virus had no clinical signs of AIDS but had developed a nerve disorder that limits sensation in the arms and legs. This finding suggests that patients who harbor the AIDS virus may develop neurologic disease before, or instead of, AIDS itself.

NINCDS intramural scientist Dr. John L. Sever and his colleagues are collaborating with Dr. Roger Detels of the University of California at Los Angeles on an epidemiological study attempting to identify preventable factors in the development of AIDS. The investigators are monitoring a large group of homosexual men in Los Angeles to determine whether certain sexual practices, drug use, disease histories, or viral infections (other than HTLV-III) are related to the disease.

In an effort to develop a useful animal model for AIDS, members of Dr. Gajdusek's laboratory, together with a team of investigators from the NCI and the Pasteur Institute in France, attempted in 1984 to transmit human AIDS to chimpanzees. Observations continued this year showed that the immune systems of the inoculated animals reacted to the AIDS virus. No clinical signs of infection have yet developed. Because the incubation period of the virus is as yet undetermined, the investigators will monitor the chimpanzees for indications of immune deficiency or encephalopathy for several more years.

In tests of other possible animal models, Drs. Gajdusek and Gibbs this year injected HTLV-III into horses and newborn rhesus monkeys. Horses were selected because equine infectious anemia is caused by a virus with a structure similar to HTLV-III. Drs. Gajdusek and Gibbs found that the horses develop antibodies to the virus, but like the chimpanzees inoculated earlier, they have not developed overt signs of AIDS.

Newborn rhesus monkeys were chosen because, when infected with a retrovirus similar to HTLV-III, they develop an encephalopathy that is indistinguishable from that seen in human AIDS patients. The scientists will follow the young monkeys to see if they develop an encephalopathy now that they have been inoculated with the AIDS virus.

An NINCDS intramural research team headed by Dr. Sever has been studying an AIDS-like disease in rhesus monkeys called Simian Acquired Immunodeficiency Syndrome (SAIDS). Studies of the SAIDS virus might reveal how retroviruses cause immune suppression and may lead to ways to prevent and treat this monkey disease and its related human counterpart.

This year, Dr. Sever's team, which includes Drs. Maneth Gravell and William T. London, developed two possible SAIDS vaccines: one made by attenuating, or weakening, the SAIDS virus so it reproduces in the body but does not cause disease; the other, derived from a virus closely related to the SAIDS virus. To determine if these vaccines work, the scientists will measure the antibody response of the rhesus monkeys and test the animals' resistance to fully potent SAIDS virus. The investigators hope that development of a SAIDS vaccine will provide valuable information about the procedures needed to develop a vaccine against AIDS. A SAIDS vaccine will also help protect the rhesus monkey, a valuable research animal, against disease.

In related work with monkeys, Dr. Sever and his group reported this year that urine and saliva can transmit the SAIDS virus, suggesting these body fluids are the likely vehicles for the spread of the natural disease in primates.

A detail of the AIDS virus that has puzzled scientists is its physical appearance. In pictures taken with an electron microscope, the central core of the virus isolated from human tissue sometimes appears as a bar, a triangle, or a large dot. The same physical variations were seen when the SAIDS virus was isolated from monkeys. Dr. Sever and his team reported this year that the appearance of the AIDS and SAIDS viruses varies depending upon how specimens containing the virus are sectioned for study under the electron microscope. This information should be useful for classifying these infectious agents and for identifying the viruses in clinical tissues.

National Institute of Allergy and Infectious Diseases

A number of investigations conducted and supported by the NIAID are focused on developing safe and effective treatments for both the underlying immune deficiency and the host of devastating illnesses that kill persons with AIDS. Another research priority, the establishment of an animal model for AIDS, is a crucial element in the eventual development and testing of a vaccine, and would further speed research on treatment. Other studies are designed to trace the incidence of AIDS in various populations to determine what factors are common among those who develop symptoms, and how the virus is transmitted from person to person. This information is essential for devising education and prevention strategies that can reduce risk of infection and decrease incidence of the disease in the population.

Dr. Anthony S. Fauci, Director of the NIAID, occupies a vanguard position in the battle against AIDS. A major objective of the research conducted by Dr. Fauci and his associates in NIAID's intramural program is to understand precisely what happens to destroy the immune system of patients with AIDS. Dr. Fauci and his colleague, Dr. H. Clifford Lane, have pinpointed the critical immunologic defect resulting from attack by the virus that causes AIDS.

They found that the virus selectively destroys or inactivates a particular subset of the lymphocytes (white blood cells) that are responsible for the induction and regulation of the body's immune function. These cells, called helper/inducer T lymphocytes, normally detect invading infectious agents. They respond by proliferating and by recruiting other immune cells into action.

Drs. Fauci and Lane also confirmed that other T lymphocytes, called suppressors, continue to operate normally. A series of laboratory studies led the investigators to conclude that the essential immune defect in the patient with AIDS is a lack of helper function rather than overabundant suppressor function. A defect of such selectivity is unprecedented in previously recognized immune deficiency states. Knowledge of the precise mechanisms responsible for the devastating impact of the virus on the immune system is critical in designing appropriate therapies.

Following the discovery of the causative agent of AIDS and the identification of how the virus attacks the immune system, the NIAID intramural research program has made a major shift into studies on therapies.

NIAID scientists are utilizing a two-pronged approach in treating the underlying immunodeficiency of AIDS.

Reconstitution of the immune response is one arm of this effort; direct attack on the AIDS virus is the other.

Before the causative agent of AIDS was identified, Drs. Lane and Fauci attempted to reconstitute the immune system in a patient with AIDS, by giving him bone marrow and lymphocytes from his healthy identical twin. Definite improvement in the immune system occurred, but the effects were only transient.

The identification of the virus that causes AIDS has prompted studies by Drs. Lane and Fauci using a combination of antiviral drugs and immune enhancers in several other sets of twins. Each twin with AIDS receives suramin, an antiviral drug, in order to suppress or perhaps eliminate the virus, and transfusions of lymphocytes and bone marrow from his healthy twin. Results of these studies will not be available for some months, but if the approach proves successful it could serve as a model treatment regimen in other AIDS patients.

Another method of boosting the immune system is to administer interleukin-2 (IL-2), which stimulates T cell activation. Because the T cells are not activated normally in patients with AIDS, Drs. Lane and Fauci, over the years, have treated these patients first with natural IL-2 and later with IL-2 made by recombinant DNA technology. Results thus far indicate that IL-2 can cause an increase in lymphocyte count and a minor reduction in Kaposi's sarcoma tumors. These changes provide firm evidence that IL-2 may play an important role in potential combination treatment regimens.

The NIAID has initiated a 5-year intramural clinical trial of suramin to assess the ability of this antiviral drug to inhibit replication of the virus in patients with AIDS and AIDS-Related Complex (ARC). Patients with AIDS and ARC will be involved in the study. Results of a preliminary study of suramin in a small number of patients with AIDS were reported by Drs. Fauci and Lane, in collaboration with NCI colleagues. Although no clinical or immunologic improvement occurred, the virus level fell in some patients and became undetectable in others. Other antiviral substances in addition to suramin, including foscarnet, ribavirin, and HPA-23, are also being tested in patients by NIAID intramural investigators and NIAID grant or contract-supported scientists.

Investigators at NIAID and at many outside institutions supported by the Institute are also searching for effective ways to treat the numerous opportunistic infections that overwhelm the weakened immune systems of patients with AIDS. One of these, progressive cytomegalovirus (CMV) infection, can lead to retinitis, blindness, colitis, pneumonia, and death. Drs. Lane and Fauci, in collaboration with NEI scientists, have reported encouraging results using DHPG, an antiviral drug, to treat AIDS patients who had severe CMV retinitis. DHPG is chemically similar to acyclovir, a recently licensed drug that is effective against herpesvirus infections. DHPG, also known as BW B759U, has been evaluated both preclinically and clinically through NIAID-funded activities.

Development of a vaccine is imperative, in view of the sharply rising incidence of AIDS and ARC, and the estimated large numbers of persons who are potentially infectious.

Scientists generally have assumed that an AIDS vaccine would contain the glycoproteins (carbohydrate-protein compounds) on the envelope, or coat, of the virus. This assumption has been supported by observations that antibodies from the blood of patients with AIDS or ARC, and from the blood of healthy persons who are seropositive (having antibodies to the AIDS virus), bind to two major glycoproteins in cells infected with the AIDS virus.

Using new scientific technology, NIAID intramural scientist Dr. Malcolm Martin and his colleagues have demonstrated that viral isolates obtained from several patients in the United States and Africa show substantial differences in the envelope glycoproteins. This variability may complicate efforts to generate a vaccine, as it may be necessary to direct vaccine and therapy efforts against other, less variable viral proteins.

NIAID supports a number of studies on AIDS, covering a wide variety of disciplines, that are being conducted by Dr. John Fahey and his associates at the University of California at Los Angeles. One of their recent findings supports previous evidence, gathered by a number of researchers, that only a relatively small proportion of persons who are exposed to the AIDS virus will develop AIDS. In a study of homosexual males whose blood tests revealed antibody to the AIDS virus, two distinct immunologic patterns emerged. In one group, the number of helper T lymphocytes decreased and then remained at a plateau; in the other, smaller group, the helper T lymphocytes continued to decrease in number and these persons went on to develop AIDS.

Dr. Thomas Quinn of NIAID's intramural program is working with an international team of associates to study the prevalence of AIDS virus infection in high-risk populations in Nairobi, Kenya. In a group of 90 female prostitutes, they found 54 percent were seropositive for HTLV-III. More than 75 percent of the seropositive women had evidence of significant clinical disease, with generalized lymphadenopathy (swollen lymph glands) and/or T-cell ratio reversal (more suppressors than helpers). None, however, had opportunistic infections, Kaposi's sarcoma, or symptoms affecting the whole body.

The NIAID is supporting a multi-center cohort study to examine prospectively the natural history of AIDS in more than 5,000 homosexual men in four cities. Dr. John Phair, NIAID contractor at Northwestern University Medical School, Chicago, has reported early results from this study. The data suggest that prevalence of HTLV-III antibodies in homosexual men varies across the United States, that transmission is occurring at a high rate, and that homosexual men can probably reduce their risk of AIDS by decreasing the numbers and altering the types of their sexual contacts.

Some evidence exists that homosexual men are altering their sexual practices in response to the AIDS epidemic. Dr. Walter Stamm, an NIAID grantee at the University of Washington, Seattle, and his colleagues have studied a population of homosexual men who were seen in a sexually transmitted diseases clinic in 1980-81 and in 1983-84. All the patients had symptoms of proctitis (inflammation of the rectum) or enteritis (inflammation of the intestine), and none had overt signs or symptoms of AIDS or ARC. The number of sexual contacts during the 6 months before examination was comparable in the two groups. Data collected by the investigators led to the conclusion that the practice of rectal intercourse had declined, as had transmission of gonorrhea, the major disease spread by this route.

Dr. Gerald Friedland, a grantee at Albert Einstein College of Medicine, Yeshiva University, New York, and his colleagues are conducting a prospective investigation of the risk of transmission of AIDS virus to household members (but not sexual contact) living with adult AIDS patients. They studied 88 household members none of whom had risk factors for AIDS, including children, siblings, parents, and other relatives of 35 patients with AIDS. Contact with the patients extended over a number of months before and after onset of the patients' symptoms, and included sharing the use of bathrooms and kitchens as well as sharing a number of personal items (such as clothes, towels, and drinking glasses). Personal interactions included hugging and kissing the patients. No household members developed AIDS or ARC. Only one, a 2-year-old biologic child of a patient with AIDS, had a positive HTLV-III antibody test. The investigators concluded that, even after prolonged contact with patients with AIDS, people sharing households are at minimal risk for nonsexual transmission of HTLV-III infection.

National Eye Institute

The National Eye Institute (NEI) is participating in the research effort on AIDS. Studies conducted at the NEI's clinical research facilities are expected to yield important information about the disease, its detection, and possible treatments.

During the past year, NEI and NCI investigators found that the virus responsible for AIDS, HTLV-III, could be detected in the tears of a patient with this disease, and also in the outer layer of the conjunctiva, the transparent membrane that covers the white of the eye and the inside of the eyelids. The recovery of HTLV-III from tears and conjunctival epithelium is consistent with recent studies isolating HTLV-III in other tissues and secretions from AIDS patients, including the blood, semen, saliva, brain, and bone marrow.

In the tear study, the NEI researchers definitively isolated HTLV-III in the tears of 5 of 15 AIDS patients. Laboratory tests did not, however, reveal any sign of the virus in tear specimens collected from normal control individuals. In the study of conjunctival tissue, the virus was detected in 3 of 10 AIDS patients and in none of the controls.

These findings point to the existence of a previously unsuspected reservoir of the AIDS virus--the conjunctival epithelium. The conjunctival and corneal epithelia are both squamous (scalelike), and bits of tissue readily slough off upon mild irritation. It is possible that cells containing HTLV-III are sloughed off into tears or onto instruments which contact the eye. These findings were reported by NEI and NCI to the Centers for Disease Control (CDC), which responded by outlining precautions to be taken to prevent spread of HTLV-III and other microbial pathogens through tears and ophthalmic instruments. At the same time, the CDC stressed that there has been no evidence to date that the disease can be transmitted through casual contact with the bodily secretions of affected individuals, nor through medical instruments used to examine them.

Scientists at the NEI and NIAID are also studying AIDS-associated ocular infections. The major cause of loss of vision in people with AIDS is a viral infection of the retina caused by cytomegalovirus (CMV). The investigators have learned that AIDS patients with CMV retinitis are at high risk of dying within a few months, apparently because they are in a severely immunosuppressed state. In severe cases, blindness may precede death, thereby adding to the spectrum of problems AIDS victims face. In recent months, an antiviral drug called DHPG has been found to be effective in CMV retinitis, but the response is transient with relapses occurring as soon as the drug is discontinued. In future studies, the team of researchers will try to ascertain an appropriate maintenance dose of DHPG in an effort to preserve vision and the quality of life as long as possible.

Division of Research Resources

In 1985 approximately 18 of the 78 General Clinical Research Centers (GCRC's), supported by DRR, conducted research into AIDS.

Major abnormalities in adrenal function have been identified in AIDS patients by GCRC researchers at the University of California in San Francisco. Dr. Edward Biglieri and his associates stimulated the adrenal glands of 24 AIDS patients who had life-threatening infections and then measured the plasma levels of adrenocortical hormones. Persistent adrenal abnormalities were identified in all patients. Many AIDS symptoms, including weight loss, nausea, vomiting, and debilitation, could be specific effects of adrenal insufficiency. If so, the replacement of adrenal hormones could be beneficial in restoring well-being and could possibly influence the course of the disease.

Eye disorders are common and potentially serious complications of AIDS. In a study conducted at The Johns Hopkins GCRC, Drs. David Newsome, W. Richard Green, and their GCRC colleagues found that all 13 AIDS patients had serious eye disorders, although none experienced eye pain or other symptoms that could alert physicians to the problem. Based on these studies, the investigators recommend that AIDS patients routinely undergo eye examinations, possibly including angiography (an x-ray that uses a fluorescent dye). Studies conducted at other medical centers indicate that 42 to 53 percent of all AIDS patients have eye infections or other eye-related abnormalities, thus confirming the need for such examinations.

Toxoplasma encephalitis, a rare inflammation of the brain caused by the toxoplasma parasite, has become epidemic among AIDS patients, according to researchers at the Palo Alto Medical Foundation in California who received partial support from DRR's Biomedical Research Support Grant Program.

During a recent 30-month period, Dr. Jack Remington and colleagues at the Palo Alto Medical Foundation examined tissue and serum specimens from 85 patients with toxoplasma encephalitis; 70 of these patients also had AIDS. Previously, they had found only 10 cases of toxoplasma encephalitis in the 6 years ending in 1981.

Dr. Remington and his team hypothesize that the lower antibody response to toxoplasma found in AIDS patients may indicate that symptoms of this type of encephalitis become obvious with reactivation of a long-term infection. The reduced response may also be directly caused by the severe immune deficiency in these patients.

A simian retroviral disease of macaque monkeys called simian acquired immunodeficiency syndrome (SAIDS) is being studied extensively at the regional Primate Research Centers (PRC's) supported by DRR.

Because epidemiological evidence indicates that the AIDS virus may have originated in Africa, the investigators decided to focus their search for the newly isolated virus, known as STLV-III (simian T-cell lymphotropic virus), to monkeys native to areas of Africa where AIDS is prevalent. Dr. Phyllis Kanki and colleagues of the Harvard School of Public Health and the New England PRC, examined sera from African green monkeys caught in the wild and chimpanzees and baboons raised in captivity--all of which are natural inhabitants of central Africa. The investigators also examined human sera from healthy homosexuals as well as from patients with AIDS and AIDS-related complex (ARC)--all from the United States. They found antibodies to the STLV-III virus in sera from 42 percent of the African green monkeys. They also found antibodies that cross-reacted with viral proteins of HTLV-III in sera from 3 of the 10 AIDS patients, 7 of the 10 ARC patients, and 7 of the 12 healthy homosexuals. None of the baboon or chimpanzee sera contained the antibodies. The researchers suggest, therefore, that African green monkeys may have been the source of the STLV-III virus which was transmitted to man, and that the major proteins apparently shared by this virus and HTLV-III may be very important in developing a vaccine to prevent AIDS.

Recent studies at the Yerkes PRC in Atlanta, Georgia, and the Delta PRC in Covington, Louisiana, demonstrate that another species of monkeys may be a source of a virus similar to STLV-III or HTLV-III. Sooty mangabeys have shown a high prevalence of infection, indicated by circulating virus and specific antibody. The animals have not shown any clinical evidence of infection. According to the researchers, their findings also support the hypothesis that African monkeys may have transmitted an AIDS-like virus to humans in central Africa.

Food and Drug Administration
Acquired Immune Deficiency Syndrome

FDA is continuing its collaborative studies with the National Institute of Allergy and Infectious Diseases (NIAID) and the National Cancer Institute (NCI) in characterizing the immune responses, monitoring viral infection, and studying antiviral and immunotherapeutic drugs in AIDS patients. The treatments under study include those to treat HTLV-III infection/AIDS specifically as well as experimental therapy of cytomegalovirus infection.

FDA has performed or is performing: a) studies to verify that the processes utilized to prepare anti-hemophiliac factor (Factor VIII) and immunoglobulin are sufficient to inactivate HTLV-III; b) studies of the effects of antiviral compounds on replication of HTLV-III; c) studies of the molecular biology of HTLV-III; d) studies in primates to develop an animal model for AIDS; e) studies of the epidemiology of HTLV-III infections; f) studies of the immunology of HTLV-III infections; and g) studies of HTLV-III infections, their relationship to AIDS, and their significance with respect to safety of other biologic products. FDA is also continuing its study with the American Red Cross on virus distribution in plasma fractions. In addition, FDA is directly involved in activities related to the HTLV-III antibody test kits and to the evaluation of the safety of blood products.

HTLV-III antibody testing. Progress continues on the availability of test systems for HTLV-III antibody. By October 1985, all of the original five licensees were either granted product licenses or the granting of their licenses was imminent. The performance of licensed tests in clinical use was under investigation by FDA. A public meeting held in July suggested that the performance of the test systems licensed initially was extremely good. Performance data continue to be gathered by the FDA. FDA established a contract program with members of the blood service complex to determine the significance of donors who have repeatably reactive sera by enzyme immunoassay, but who do not have reactivity for the antibody on an additional more specific test (Western blot).

HTLV-III antibody test implementation. During the reporting period, HTLV-III antibody testing was implemented in blood banks, donor centers, and plasmapheresis centers throughout the country. Preliminary guidelines were suggested by the Centers for Disease Control (CDC) in January. In these recommendations it was suggested that donors should be notified of test results which indicated that the antibody to HTLV-III was present in their sera. Implementation of this suggestion was complicated somewhat by local laws prohibiting such notification. Nevertheless, the key aspect of protecting the blood supply, which was the removal of units from the blood supply, drawn from donors with repeatably reactive sera, was accomplished over the spring and summer of 1985. Spot surveys by the FDA suggest that HTLV-III antibody testing of donors in the United States is universal.

All registered blood establishments were issued provisional recommendations in July 1985 concerning blood or plasma previously collected from donors currently HTLV-III antibody positive. For source plasma, recovered plasma, and other blood products for further manufacturing: it was recommended that plasma intended for use in non-injectable products or for use in preparing products by a method known to inactivate viruses, the quarantine and notification procedures applicable to plasma known to be HBsAG-reactive were applicable. For plasma intended for preparing injectable products, a "look back" period of six months was recommended. All registered blood establishments were issued additional guidelines on September 3, 1985 redefining and clarifying a donor exclusion criteria as, "any male who has had sex with another male since 1977." Throughout the reporting period the FDA coordinated activities closely with key representatives of the blood service complex and industry. Thus, FDA took the lead in establishing a proactive joint venture with industry to assure the safety of the blood supply. As a result, even in the absence of a regulation concerning HTLV-III antibody testing and self-exclusion of donors, compliance appears to have been universal and the safety of the blood supply maximized through this approach.

Product safety issues. Throughout the year the safety of the various manufactured components of blood licensed by the FDA was monitored closely. Manufacturers of intravenous gamma globulin were requested to pool their data from immuno competent recipients to determine the rate, if any, of HTLV-III antibody conversion. Because most recipients of IV immune globulin are not competent to seroconvert, this combined approach was considered to be the only manner to gain sufficient numbers of subjects that some conclusions could be drawn concerning the safety of immune globulin administered intravenously. Concommitantly, laboratory studies within FDA were conducted to determine the effect of the Cohn-Oncley procedure on plasma samples to which HTLV-III was added. Representatives of industry were requested to perform similar types of studies on their individual fractionation processes, in order that a viral inactivation/partition could be validated for each manufacturer's process. Preliminary data indicate that there is significant viral inactivation during a Cohn fractionation process. The extent of the inactivation must await analysis of the final studies.

Formal regulatory initiatives. During the reporting period, a regulation concerning HTLV-III antibody testing of blood donors and plasma was drafted, widely circulated for review and cleared by the FDA. Thus, regulatory implementation of voluntary recommendations and guidelines is ready for publication as a proposed rule.

Future plans. It is expected that all the initiatives which remain incomplete will be carried forward in the future. Specifically, it is anticipated that data will become available concerning the implications of a repeatable reactive enzymimmuno assay and a negative more specific test (Western blot). It is also anticipated that the data concerning the safety of immune globulins and the inactivation of HTLV-III during the commercial alcohol fractionation process will be clarified. Monitoring of performance of existing licensed reagent kits, and those to be licensed in the future, will continue. It is anticipated that additional, more specific tests will be offered to the FDA for licensure in the near future, and the ability to more clearly characterize reactivity in blood donors will become available. Close liaisons will be maintained between the CDC and FDA regarding reported instances of AIDS which may have been acquired by blood transfusion from HTLV-III antibody negative donors. To date no such cases have been reported; however, due to the long incubation period of transfusion-transmitted AIDS, only a small number of pediatric cases would have been anticipated were the test of no value. FDA will continue to insure expeditious licensing of new products which suggest the potential as confirmatory tests. In-house efforts will continue to develop a more specific probe for HTLV-III infectivity in blood donors. It is anticipated that revised package inserts for currently licensed HTLV-III antibody kits will resolve somewhat the controversy concerning the use of the screening tests. This clarification, coupled with an additional more specific test for HTLV-III antibody presence, will ease significantly some of the contentious issues surrounding HTLV-III antibody testing.

Centers for Disease Control

Acquired Immunodeficiency Syndrome (AIDS)

AIDS continues to be a major public health problem in the United States. From December 1984 to December 1985, the number of reported cases increased from 7,661 to over 16,039, an increase of 110 percent. Nearly half of all patients with AIDS are known to have died. The significant increase in AIDS cases, coupled with the identification of the etiologic agent and the availability of the HTLV-III antibody test, has led to an expansion of activities into areas of [illegible] research, education, and control of AIDS and HTLV-III infection.

CDC will continue to focus on: national surveillance of AIDS; national and international epidemiologic studies to identify new risk factors and further define modes of transmission; development and evaluation of prevention strategies; improvement of serologic and other diagnostic tests; development of an animal model and participation in approaches for vaccine development and evaluation; transfer of technology to the medical and public health communities for widespread application; and provision of AIDS prevention information and materials to medical and public health communities, high-risk groups, and the public, in support of the overall goal to prevent the transmission of AIDS.

Cooperative agreements will continue with State and local health departments in high-incidence areas to conduct active surveillance and related epidemiologic investigations. CDC will continue to monitor and analyze national trends in AIDS incidence by geographic area and risk group, including active surveillance of patients with [illegible] and pediatric AIDS, to clarify risk factors and patterns of transmission and to formulate prevention strategies.

To further define modes of transmission and risk factors, CDC will conduct epidemiologic studies of: (1) risk factors for transmission among a cohort of homosexual men in San Francisco; (2) risk among female sexual partners of heterosexual AIDS patients; (3) AIDS patients reported not to belong to known risk groups; (4) blood donors to patients with transfusion-associated AIDS; (5) recipients of blood from persons with AIDS or infection with human T-lymphotropic virus type III (HTLV-III); (6) risk from nonsexual exposure to patients with AIDS among health care and laboratory workers; (7) prevalence of HTLV-III antibody in hemophiliacs, their sexual partners and household contacts; (8) AIDS in Africa; and (9) perinatal and heterosexual transmission.

CDC will continue laboratory investigations of HTLV-III to: (1) provide viral isolation, serologic, and immunologic support for epidemiologic studies; (2) assess sensitivity and specificity of serologic tests; (3) determine variation among virus isolates from different geographic areas as a basis for possible variability in the patterns of [illegible] response and pathogenicity; (4) determine whether detection of virus proteins and/or nucleic acid sequences are useful in rapid diagnosis of infection; (5) correlate clinical and histopathological findings with antibody to AIDS virus and positive cultures of this agent; (6) determine the immunologic responses of infection with AIDS virus; (7) determine susceptibility of AIDS virus to disinfectants and environmental conditions; (8) continue studies of primates and other animals who are infected with AIDS virus to clarify the natural history of infections; and (9) participate in approaches for vaccine development and evaluation.

As laboratory technology becomes available, it is being transferred to laboratory personnel in the private and the public health sectors who are trained to perform diagnostic procedures. Improved screening and diagnostic capabilities will permit the identification of individuals with less severe or even asymptomatic infection. An effect of this technology transfer will be a significant increase in identified infections, thus expanding prevention efforts.

CDC continues to modify prevention recommendations for risk groups, health-care workers and professionals, and the public. PHS prevention recommendations to reduce the risk of AIDS transmission were first issued in November 1982 and March 1983. Since that time, nine additional major guidelines have been developed and distributed related to prevention of AIDS and HTLV-III transmission. Other interim guidelines have been published as new information became available. Ongoing epidemiologic research continues to clarify and quantify the risk of AIDS for most groups and identify specific behaviors or susceptibility factors. The results of this research are being translated into additional prevention efforts which will be carefully evaluated in multiple settings. CDC will continue to fund and provide technical assistance to the U.S. Conference of Mayors national AIDS information interchange system among city governments. The exchange program will make timely and appropriate information about AIDS available to Mayors and local health officials, especially in high impact cities.

The strategy to control spread of HTLV-III/LAV is influenced by five crucial facts: no effective therapies exist to eliminate the virus or curtail its growth in the infected patient; there is no vaccine to prevent susceptible persons from acquiring infection; an infected individual may be able to transmit the virus continually, or intermittently, throughout his or her lifetime; (4) spread of the virus results from a few personal behaviors which, when altered, can reduce the possibility to a minimum; and (5) HTLV-III/LAV infection is the first modern infectious disease causing significant morbidity and mortality for which health education is the only instrument available to carry out an aggressive public health control effort.

The goal of the control strategy, therefore, is to reduce HTLV-III/LAV transmission by influencing the behavior of people in three specific population groups. The primary effort is to apply individually targeted health education messages to persons who are already infected so they will adopt behaviors that reduce their risk of spreading the virus to others. Second, the strategy aims to deliver risk reduction messages that will help prevent infection in people who are uninfected but whose current personal behaviors place them at high risk of acquiring an infection. Third, the strategy is designed to reach the general public with timely and accurate information that defuses unjustified fears, facilitates rational behavior toward all aspects of the AIDS problem, and promotes constructive support for the control efforts of public health officials.

Implementing this strategy requires the development in each State of a focused and cooperative community-based program which coordinates the delivery of targeted AIDS health education, plus risk reduction messages and support services necessary to reinforce them. Many States currently do not possess such programs, so CDC will award cooperative agreements in FY 1986 to help develop this capacity. Conversely, most of the high incidence of AIDS already have a number of health education and risk reduction activities under way, but need financial augmentation to expand them and enhance their overall impact. During FY 1986, CDC will fund 15 to 25 cooperative agreements for the intensification of control efforts in these high morbidity areas.

Health education techniques dominate the current strategy for controlling transmission of HTLV-III/LAV and probably would continue to play a pervasive role even with the development of effective therapies and/or a vaccine. Therefore, it is essential to identify the most effective methods of applying these techniques, test them and other evolving control measures under actual program conditions, and disseminate information to assure all States can focus their energies and resources on approaches that truly work. To accomplish these ends, CDC will award six to eight cooperative agreements in FY 1986 for research into innovative risk reduction approaches and up to eight new and continuation cooperative agreements supporting community-based demonstration projects for AIDS prevention and risk reduction.

Hemophiliacs are a special group at high risk for HTLV-III/LAV infection and AIDS. For many, their initial acquisition of the virus was unavoidable. Further transmission from and among this group, however, can be prevented. Consistent with Congressional intent, CDC plans to provide funding for a national AIDS education/risk reduction effort directed at hemophiliacs and will collaborate with the National Hemophilia Foundation and its national network of Comprehensive Hemophilia Treatment Centers in carrying this out.

In FY 1985 the Centers for Disease Control focused its efforts on the following activities:

A. Epidemiology and Surveillance
   a. Developed [illegible] for AIDS among school and foster care children.
   b. Continued studies of risk factors for AIDS among a cohort of 7,000 homosexual men through a cooperative agreement with the San Francisco Health Department.
   c. Completed a case-control study of risk factors for AIDS among Haitians living in [illegible] through cooperative agreements.

A. Epidemiology and Surveillance - cont'd

d. Investigated AIDS patients reported not to belong to known risk groups.
e. Investigated blood donors of patients with transfusion-associated AIDS.
f. Continued a study to determine risks of AIDS among family members of heterosexual AIDS patients in Bronx, New York, through a cooperative agreement to Montefiore Medical Center.
g. Continued a study of persons transfused with blood components donated by persons who subsequently developed AIDS or related disorders.
h. Continued surveillance and epidemiologic studies of AIDS and HTLV-III infection in Zaire.
i. Initiated studies of prostitutes and heterosexual transmission of AIDS and HTLV-III infection.
j. Supported 26 State and local health departments in active surveillance and related epidemiologic investigations through cooperative agreements.
k. Analyzed surveillance data to provide accurate information on AIDS trends and patterns and to detect any newly emerging risk groups.
l. Continued the assignment of Federal Public Health Advisors to New York City, San Francisco, Los Angeles, and Miami to assist with surveillance projects and other AIDS activities.
m. Produced and distributed a cumulative weekly surveillance summary of AIDS cases reported to CDC.

B. Laboratory Investigations
a. Characterized the etiologic agent of AIDS using microbiologic, serologic, and immunologic techniques.
b. Studied the role of immune complexes in AIDS patients.
c. Described unique ultrastructural findings in electron microscope studies of tissues from AIDS patients.
d. Provided laboratory support for CDC epidemiologic studies of AIDS.
e. Progressed in the development of an animal model of AIDS, particularly in the use of primates.

C. Safety of Blood Products and Blood
a. Investigated blood donors to patients with transfusion-associated AIDS.
b. Continued surveys of the occurrence of AIDS and AIDS-related illnesses among patients seen at hemophilia treatment centers.
c. Conducted studies of recipients of Factor VIII and IX concentrate
d. Evaluated sensitivity and specificity of HTLV-III antibody test among blood donors.

D. Laboratory Services and Technology Transfer
Provided training for public health laboratories in conducting Elisa (HTLV-III antibody) and Western blot tests.

E. Prevention
Awarded cooperative agreements to 55 areas to establish alternate sites for HTLV-III/LAV antibody testing so that individuals at increased risk for AIDS could determine their antibody status without attending a blood donation center.

F. Information and Education
   a. Conducted 54 1-day seminars on HTLV-III/LAV antibody testing in 34 cities during February 1985, reaching over 7,500 professionals from health departments, blood donation centers, and community organizations concerned with AIDS.
   b. Developed and presented 15 2-day courses on counseling related to HTLV-III/LAV antibody testing in 24 States.
   c. Initiated an information sharing network to periodically keep State and territorial health officials informed of developments and results from HTLV-III/LAV antibody alternate site testing.
   d. Accepted responsibility for the PHS National AIDS hotline and managed its increasing usage to the current level of about 29,000 calls per month (8,000 with a live response, 21,000 with a taped message).
   e. Conducted 2 national sessions for local AIDS hotline directors to facilitate the exchange of ideas and recommendations.
   f. Published 45 articles in Morbidity and Mortality Weekly Report (MMWR) in FY 1985.
   g. Distributed thousands of AIDS information materials, including copies of MMWRs, journal articles, and question and answer sheets.
   h. Provided speakers for educational institutions and numerous National, State, and local professional and lay audiences.
   i. Handled numerous interactions with representatives of the print and electronic media.
   j. Cosponsored, with other PHS agencies, an International Conference on AIDS to disseminate scientific and public health information.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute of Mental Health

Acquired Immunodeficiency Syndrome (AIDS)

Extramural Research

During FY 1985 NIMH provided support for 17 research projects focused on the psychiatric, biobehavioral, and psychosocial aspects of AIDS including studies focused on the relationship between psychological conditions and immune function, developing and testing of psychological and behavioral measures to assess mental health status as it relates to AIDS, changes in high risk behavior patterns, the correlation of behavior changes with immunological status in large samples over time, and psychological reactions to the HTLV-III blood test. The total expenditure for AIDS related research in FY 1985 was $1,802,178.

The following abstracts indicate interim findings or major hypotheses relevant to current research.

1. Investigators are studying the hypothesis that persons with antibody to HTLV-III will show increased incidence of AIDS and AIDS-Related Conditions (ARC) with increased stress and depression, and decreased incidence with increased social support and coping skills. The investigators are also studying relationships between psychosocial and immunological variables in antibody positive and antibody negative individuals. (Coates, MH39343-02)

2. Investigators are exploring the impact of AIDS using conceptual frameworks from the literature on stress. The state of knowledge on stress is such that the psychological impact of stressful events on specific populations can be measured with reasonable reliability. These investigators are collecting longitudinal data on the impact of this major epidemic on the members of the community most severely affected. (Coates, MH39553-02)

3. According to this investigator, the only current method of reducing the spread of the disease is through behavioral changes.

   In conjunction with the UCSF AIDS Clinical Research Center, a symposium was held at the University of California San Francisco on intervention strategies for high risk behavior. As a result, they derived a measure of overall sexual risk taking. The investigators also delineated a health belief model related to AIDS. They are refining this model and have identified predictors of change in sexual behavior as well as positive and negative adaptations to the AIDS crisis. (Coates, MH39553)

4. The investigators have data suggesting the patterns of intimacy are changing in the gay community, have positively adaptive health value, both from medical and psychological perspectives, and are related to sexual behavior. Those men who are in primary relationships engage in less high risk sexual activity both with their partner and with others and appear to be healthier psychologically and physically. Therefore, it is important to focus on the definition, development, and maintenance of intimacy patterns since these also have become adaptive to the threat of AIDS.

   Changes have occurred in all behaviors considered to be high risk inside primary relationships. Respondents are having fewer numbers of sexual partners, and a lower frequency of high risk sex with secondary or anonymous contacts.

   The level of monogamy in existing relationships has remained stable and the proportion of men in relationships continues to remain relatively stable over time. This may be due in part to sampling bias since one quarter of the sample is men in stable relationships. Therefore, a different measure of patterns of intimacy needs to be taken to understand the impact of AIDS on relationship formation and maintenance.

   Number of friends, negative stress reduction strategies, and stress were positively related to risk score, while positive stress reduction and being in a primary relationship were negatively related to risk score. This suggests that the inability to manage stress and some aspects of social networking are related to high risk sexual activity. More attention needs to be devoted to specifying the nature of social support related to high and low risk sexual behavior.

   Men in relationships were more likely to be making positive healthful adaptations to the AIDS crisis than those not coupled. Couples generally experienced lower risk, less stress, and engage in more positive free time activities. Monogamous couples show significantly higher personal efficacy, skills, attainment, and self esteem. (Coates, MH39553-02)

5. While professional and gay organizations have disseminated sexual guidelines, little data exists on the extent to which they have been adopted. Data were analyzed from the first 54 asymptomatic homosexual males accrued as controls in a study of modifications in sexual practices. Subjects were asked whether they had adopted each of the five modifications since learning of the AIDS epidemic. The data revealed 83% had fewer different sexual partners; 74% had fewer anonymous partners; 30% had increased their use of condoms; 28% were more often insisting that partners use condoms; and 38% had reduced their use of drugs with sex. About 15% had not adopted any modifications in their behavior and the same percentage had adopted all 5 modifications. (Siegel, MH39551-02)

6. Groups of persons with AIDS and ARC appear to be highly distressed and at high risk for psychosocial difficulties. In both groups, there had been long periods of treatment delay and uncertainty about diagnosis in the months preceding actual diagnosis of AIDS or ARC.

   The most consistent and striking finding was that the ARC group is significantly in need of more psychosocial intervention than had been previously understood. Further analyses will determine whether persons with ARC remain so distressed over time, and how diagnosis of AIDS in some of these persons influences these measures. (Temoshok, MH39344)

7. A pilot study supported by NIMH (1 R03 MH39326-01) examined psychological distress and cognitive dysfunction at three points in the early course of the AIDS spectrum disorders (i.e., diagnosis, one month later, two months later) in patients with AIDS and patients with a high risk for AIDS disorder (i.e. generalized lymphadenopathy), as compared to healthy controls. A followup study is intended to extend the controlled prospective study of the prevalence and severity of psychological distress and during the later course of these disorders (i.e., six months and one year post-diagnosis). Since the group of patients carrying the diagnosis of AIDS live in closest proximity to these stresses, it is hypothesized that they are at higher risk for reactive psychological disturbance than either of the other subject groups. In addition, since AIDS-related neurological complications have recently been observed to impair intellectual functioning, it is also hypothesized that the group of patients with AIDS will demonstrate a higher rate of acute cognitive deficits than either of the other subject groups. (Holland, MH39326 and MH46789)

8. An investigator not supported by NIMH has recognized that afflicted patients frequently suffer a variety of central nervous system (CNS) complications. While some of these are well recognized opportunistic conditions, much more common is a progressive encephalopathy which has not previously been described in other immunosuppressed patients. In adults this encephalopathy characteristically manifests as a subacute dementia accompanied by motor dysfunction. The term AIDS dementia refers to this clinical syndrome. In children with AIDS, a similar encephalopathy is also common. The investigator describes recent developments in the clinical and pathological characterization of this disorder and discusses the accumulating evidence supporting the hypothesis that it results from direct brain infection by the virus which causes AIDS. (Price, "AIDS Encephalopathy") A currently supported NIMH project is continuing to explore AIDS dementia (Holland MH46789).

9. An investigator using an animal model (mice) has been exploring the relationships between the nervous and immune system, and behavior. He has shown that conditioning of a cell mediated immune response is possible and that enhancement as well as suppression of immune function can be conditioned. (Ader K05 MH06318)

Intramural Research

Dr. David Rubinow at the Biological Psychiatry Branch, NIMH, is continuing to collaborate with other NIH researchers to assess neuropsychiatric dysfunction in patients with AIDS. The purpose is to obtain longitudinal psychiatric evaluations of patients with AIDS.

Educational Activities

NIMH convened a workshop which included six recipients of research grants and selected NIMH staff to prepare a monograph on the psychological aspects of AIDS for health and mental health professionals. The Office of Scientific Information has prepared a draft which has been submitted to numerous organizations for comment and suggestions. It is anticipated that it will be cleared for publication and be widely disseminated in 1986.

FISCAL YEAR 1986

For FY 1986, the National Institute of Mental Health (NIMH) proposes a series of activities to reduce the spread of AIDS and to address the mental health consequences. NIMH activities will focus on populations at risk in regard to their concerns about AIDS, the concerns of their families and associates, and the concerns of health care providers, employers, and the general public. The activities are consistent with the goals and objectives of the Public Health Service Plan for the Prevention and Control of Acquired Immune Deficiency Syndrome. These include:

1. Continue to provide research support for projects focused on the neuropsychiatric, biobehavioral, and psychosocial aspects of AIDS, including the stigma of the disorder.
2. Develop and disseminate information to groups at risk, health and mental health care providers, employers, and the general public about AIDS.
3. Provide information and technical assistance to treatment and service providers on methods and procedures to care for the mental health needs of AIDS patients or populations at risk.
4. Participate in the Public Health Service Executive Task Force on AIDS and coordinate efforts with other Federal and private agencies.
5. Participate in the planning of the NIMH Consensus Development Conference entitled "Impact of Routine HTLV-III Antibody Testing of Blood and Plasma Donors on the Health of the Public," June 24-25, 1986.

The following planning mechanisms are either currently utilized or under discussion:

- Planning for AIDS activities is carried out at the ADAMHA level through the AIDS Policy Board and the Executive Task Force on AIDS. The Director, NIMH and key staff participate on the Working Group for Psychological, Psychiatric, and Addictive Aspects of AIDS, chaired by the ADAMHA Administrator.

- NIMH has constituted an AIDS Advisory Board composed of outside experts and staff to coordinate and provide consultation on future activities.

- NIMH is planning to coordinate with NIAID and NCI to facilitate research studies focused on the neuropsychiatric aspects of AIDS.

- NIMH has taken the lead in issuing with NIDA and NIAAA a joint RFA to stimulate AIDS research.

In FY 86, NIMH plans to make awards to two research and development centers to provide a structure for bringing research, education, and dissemination activities into a coordinated unit. The centers are conceptualized as facilitating the rapid dissemination of new knowledge into clinical practice, and to the research and training communities. NIMH plans to provide $250,000 for each center in the first year, and up to $500,000 the second year.

NIMH will prepare a Request for Applications in this area to be issued in early FY 86. This will ne an open competition for center support, with no pre-selection of sponsoring institutions. Because of the lead time required by the field for proposal preparation and the peer review process, this RFA will be issued to permit funding in FY 86.

An approach for a communication strategy for dealing with the public fear of AIDS has been developed by NIMH. NIMH has convened a group of experts to discuss issues and to develop a plan. A meeting was held September 13, 1985. Also, a planning conference on Social and Ethical Aspects of AIDS was held in New York, October 11-12, 1985.

NIMH also plans to bring together the investigators currently supported who are developing inventories which measure psychosocial and mental health aspects of AIDS. A workshop to synthesize finding and to identify areas in need of future research will be planned for early FY 86.

Fiscal Year 1987

For FY 87, NIMH will continue to provide research support for projects focused on the psychiatric, biobehavioral and psychosocial aspects of AIDS. NIMH plans to develop research grant and contract solicitations in the following areas: 1) relationships between psychological conditions and immune function; 2) development and testing of psychological and behavioral measures to assess mental health status as it relates to AIDS; 3) neuropsychological factors involved in AIDS; 4) stress and coping with a terminal illness and stigma; and more generally, death and dying; and 5) psychological reactions to receiving a positive result on the HTLV-III blood test. Research in these areas will be continued in future years with an increased number of awards. As research findings indicate new areas requiring knowledge development, the focus may be modified or redirected, particularly as AIDS spreads to different segments of the population.

NIMH AIDS AND AIDS-RELATED RESEARCH

FY 1985

(Those concerned with co-factors are noted with an asterik*)

RESEARCH GRANTS

Investigator: Lydia Temoshok, Ph.D. (2 R01 MH39344-02)*
Institution: University of California, San Francisco
Title: A Longitudinal Psychosocial Study of AIDS Patients

In FY 83, Dr. Temoshok received a two year grant to study psychological and behavioral consequences of having suspected or diagnosed AIDS. Immunological functions of subjects will be correlated with clinical and psychological conditions to study relationships of psychological factors, the immune system, and physical illness.

Investigator: Jill Joseph, Ph.D. (2 R01 MH39346-02A1)*
Institution: University of Michigan
Title: Coping Strategies in AIDS Patients

This research focuses on developing and testing psychological and behavioral measures used in AIDS research. Specifically, the investigator hopes to: (a) study relationships among psychosocial variables and measures of immune function and physical health; (b) quantify the extent of changes in sexual behavior that are presumed to affect an individuals's risk for contracting AIDS; (c) examine factors associated with the maintenance or impairment of psychological and social functioning in response to the threat of an epidemic of fatal illness.

Investigator: Karolynn Siegel, Ph.D. (5 R01 MH 39551-02)*
Institution: Memorial Hospital for Cancer, New York, New York
Title: AIDS Risk Groups: Predicting Changes in Sexual Practices

This study attempts to identify psychosocial factors associated with changes in sexual and drug related practices of AIDS patients and those at risk for AIDS, and the extent to which they comply with treatment or monitoring regimens. Factors to be examined include: social support, self-esteem, anxiety, depression, and perceived risks. The sample population will include asymptomatic homosexual males not diagnosed with AIDS or lymphadenopathy, homosexual men with generalized lymphadenopathy, and homosexual male AIDS patients.

Investigator: Jimmie Holland, M.D. (1 R01 MH 46789-01)
Institution: Memorial Hospital for Cancer, New York, New York
Title: Follow-up of Psychological Adjustment of AIDS Patients

A study of the psychological adjustment in three groups of male homosexuals: Those diagnosed with AIDS; patients at risk for AIDS such as those with lymphadenopathy; and a control group of health subjects. The groups will be compared for prevalence and nature of psychological distress and cognitive dysfunction. Changes in distress associated with the course of treatment of AIDS will be monitored to identify service needs of all groups for the development of therapeutic and prevention programs. The continuing research will focus on a prospective evaluation of psychological and social adjustment in patients with AIDS, patients at high risk for AIDS, and asymptomatic gay men. Goals of this research are to provide a profile of these patients, and alert clinical personnel to the major psychological stressors in the course of AIDS spectrum disorders, so that potential crises may be prevented.

Investigator: Paul Jacobsen, Ph.D. (R08 MH 41228)
Institution: Cornell Univ. Medical Center, New York, New York
Title: Psychological Reactions to Learning HTLV III Test Results

To identify the psychosocial impact of receiving the results of the antibody test for HTLV-III. The study will use both retrospective and prospective strategies to assess the following variables: psychiatric symptoms, psychosomatic symptoms, sexual practices, health related behaviors, and fear of developing AIDS.

Investigator: Thomas J. Coates, Ph.D. (2 R01 MH 39553-01)*
Institution: University of California, San Francisco
Title: Impact of AIDS on Sexual Behavior of Gay Men

This study changes over time related to the social and psychological functioning regarding high risk sexual behaviors, health behaviors, intimacy patterns, and psychiatric symptoms. Dependent measures will be examined in the context of knowledge of health guidelines, sources and modes of receiving information, personal beliefs about AIDS transmission, attitudes and behaviors regarding intimacy patterns, and individual differences in psychological reaction to the AIDS crisis.

Investigator: John L. Martin, Carole S. Vance, Ph.D.*
(5 R01 MH 39557-02)
Institution: Columbia University, New York, New York
Title: Mental Health Effects of Aids on At Risk Homosexual Men

This study is assessing the mental health and behavioral effects of the epidemic of AIDS on homosexual males (700) who do not have AIDS, but are at high risk. Data will be collected through two face-to-face interviews. The methodology will include both retrospective and prospective components. Outcome measures will be specific and non-specific psychological distress, drug use, and sexual behavior.

Investigator: Thomas J. Coates, Ph.D. (5 R01 MH 39343-02)*
Institution: University of California, San Francisco
Title: Prospective Psychosocial Study in Men at Risk for AIDS

This is a collaborative effort with a contract funded by NIAID entitled "A Prospective Sero-Epidemiological Study of AIDS in Homosexual Men Residing in San Francisco". Under the NIAID study a probability sample of disease free single males (1000 homosexual and 200 heterosexual) 25-54 years of age will be recruited; it is estimated that between 45-75 cases of AIDS will develop during a four year follow-up. Each subject will receive a physical examination and donate specimens for serological, virological, and chemical risk factors for AIDS; (2) the attitudes, behaviors, and beliefs of the cohort over time; (3) psychosocial consequences of diagnosis of AIDS or of symptoms possibly associated with later development of AIDS; and (4) exploration of psychoneuroimmunological relationships.

Investigator: Christopher Coe, Ph.D. (5 R01 MH/NS 40144-01)*
Institution: Stanford University
Title: Psychosocial Stress and Immune Responsiveness

This project will investigate the development of a nonhuman primate model for assessing the effects of psychologically induced stress on immune responses. The research will document the qualitative and quantitative effects of elevated cortisol levels on basic immune parameters in separated maternal and newly weaned.

Investigator: Steven Schleifer, M.D. (1 R01 MH 39651-01)*
Institution: Mt. Sinai School of Medicine
Title: Major Depressive Disorder and Immune Function

This project will investigate the association between clinical depression and immunity. Immune function will be examined in drug free patients with mild and severe depressive disorders and compared with matched controls, mediated depressed subjects, and patients in remission. The research could contribute substantially to understanding ways in which the central nervous system regulates immunity.

Investigator: Rosa T. Canoso, M.D. (R01 MH 39528-01)
Institution: U.S. Veterans Administration Hospital, Massachusetts
Title: Chlorpromazine Immunogenetics and Tardive Dyskinesia

The study is one of the first examples of the involvement of autoantibodies in major psychoses. The prevalence and severity of tardive dyskinesia will be correlated with the presence of antibodies. Follow-up studies will determine changes in the immunoneurological, neurological, or psychological parameters after discontinuation of chlorpromazine.

Investigator: Richard Pillard, M.D. (2 R01 MH 32170-01A1S1)
Institution: Boston University
Title: Clinical and Family Study of Sexual Orientation

This research is focused on the study of the familial and clinical aspects of homosexuality. It will document psychiatric disorders in homosexuals, family patterns of homosexuality, and gender-specific attributes of behavior. The research may provide a basis for further studies of genetic, hormonal, or longitudinal-developmental studies focused on the origins of sexual orientation.

Investigator: Robert Ader, Ph.D. (5 K05 MH 06318-15)*
Institution: University of Rochester
Title: Psychoneuroimmunology

This research is focused on understanding the regulation of immune responses by behavioral processes operating through the central nervous system and the endocrine system. Documentation and elaboration of the relationship between the central nervous system and the immune system has potential consequences for understanding the immune processes and clinical implications concerning chemotherapy in treatment regimens. The capacity of conditioning to suppress or enhance immune responses raises issues regarding the modifiability of the immune system and the integration of biologic and psychologic function. The results will contribute to an understanding of psychoneuroimmunology and the adaptive process. Animal subjects (rats and mice) are used in this research.

Investigator: Richard D. Todd, M.D. (1R01 MH 40841-01)
Institution: Washington University, St. Louis, Missouri
Title: Immunological Analysis-Brain Serotonin Binding Proteins

The investigators have solubilized and characterized several high affinity serotonin binding proteins from cortex. In addition, they have shown that a subgroup of autistic children possess antibodies directed against these sites. In an extension of these studies, this proposal outlines strategies to isolate and/or develop antibodies against human brain serotonin binding proteins. The long-term objectives of these approaches are to develop and utilize immunological tools to aid in the better definition of the contributions of neurotransmitter receptors and immunologic mechanisms to normal neurodevelopment and severe psychiatric disorders of childhood.

Investigator: Francis Cohen, Ph.D. (1 R01 MH41003-01)*
Institution: University of California, San Francisco
Title: Stress, Psychoimmunology, and Herpes Recurrence

This study uses recurrent genital herpes as a model to study the relationships among stress and emotional factors, immunological change and disease outcomes. The objectives are: 1) to determine the relationship between stress, mood, social support and coping and genital herpes simplex recurrence in a sample of patients with frequent outbreaks of the disease; and 2) to determine whether changes in natural killer (NK) cell activity and numbers of helper and suppressor T cells mediate the hypothesized relationship of psychosocial factors to recurrence.

Investigator: Ronald Glaser, Ph.D. (1 R01 MH40787-01)*
Institution: Ohio State University, Columbus, Ohio
Title: Personality, Psychological Stress, and Immunocompetence

The interactions among the nervous system, the endocrine system, and the immune response are now recognized as important for health. Data from a number of studies suggest that various stressors may affect the development of infectious and malignant disease through their impact on the immune response. However, very few students have used human subjects, and almost nothing is known about the immunological sequelae of repeated stressful events in humans. Since repeated stressful events have important effects on immune function and health, fluctuations in immune function will be measured in health adults following repeated exposure to the same stressor.

Investigator: Andrew H. Miller, M.D. (1 R03 MH 40903-01)*
Institution: Montefiore Medical Center, Bronx, New York
Title: Altered Immunity in Major Depressive Disorder

The competence of the immune system is an important factor in the pathogenesis of disease. Current work suggests that relationships exist between emotional states (especially depression) and impaired immune functioning. The long-term objectives of the proposed work is to further investigate this interaction between the central nervous system and the immune competence. Initially, attention will be paid to the depressive disorder.

The present study is designed to test the following hypotheses: 1) Patients with a Major Depressive Disorder (MDD) defined by Research Diagnostic Criteria (RDC) will have an impaired (altered) immune status as compared to non-depressed, healthy controls, 2) The altered immune status will be associated with those depressed patients who exhibit plasma hypercortisolemia, and 3) The altered immune status will be a function of the "state" of the depressed individual; not a "trait" function (i.e., the alteration will disappear upon resolution of the depression). To accomplish the goal, immunologic function and cortisol secretion will be measured in twenty hospitalized and twenty clinic patients diagnosed with MDD by RDC criteria. All forty patients will be age, sex, and race matched with normal controls. Immunologic function will be measured by using Natural Killer Cell Activity (NKCA) assays, lymphocyte proliferative assays, and Delayed Cutaneous Hypersensitivity (DCH) reactions. Cortisol secretion will be assessed by serial serum measures taken over a three hour period. To examine the hypothesis that altered immune competence in depression is a function of the depressed state (like plasma hypercortisolemia), patients will be studied longitudinally; before treatment, during treatment, and upon recovery.

APPENDIX

ACQUIRED IMMUNODEFICENCY SYNDROME (AIDS)

Through it's research and direct operations activities, NIDA has over the past two years begun to address the relationship between drug abuse and AIDS. NIDA is concerned with AIDS because intravenous drug users constitute a significant proportion of individuals with AIDS. Nationwide, approximately 63 percent of the cases of AIDS are among non-IV using homosexual men, 8.5 percent are among homosexual IV drug users, and approximately 17 percent are among heterosexual intravenous drug users. AIDS is transmitted among intravenous drug users primarily when needles and other paraphernalia used to inject drugs are shared.

There is considerable variation in the incidence and prevalance of AIDS from one geographical region to another. Five states--New York, California, Florida, New Jersey, and Texas--have three-quarters of all AIDS cases. In the New York area, 38 percent of reported AIDS cases have history of IV drug use, while in California, 17 percent of AIDS cases have such a history. Pediatric cases represent less than 1-1/2 percent of the total AIDS cases; however, 52 percent of these children have an IV drug-using parent.

Approximately 44 percent of those entering detoxification programs in New Jersey tested positive for antibodies to the human T-cell lymphotropic virus (HTLV-III), the virus that causes AIDS, and one-third of those in methadone maintenance programs tested positive. About 99 percent of the drug users in this study reported sharing their needles. In other areas of the country, such as New Orleans where intravenous drug use rates are high but large-scale needle sharing is not common practice, lower numbers of AIDS cases occur among IV drug users.

Research Programs

Until a cure and/or vaccine is developed, the major goal of NIDA is to keep the number of new AIDS cases as low as possible by reducing the number of individuals exposed to the AIDS virus. This will require fundamental changes in lifestyle for people at risk of exposure. We are pursuing a vigorous effort towards this end, but there are complex issues involved. One of the major tasks facing us is to assess more accurately the spread of the AIDS virus among the drug using population. Because the incubation period for AIDS is prolonged and most individuals with the virus are asymptomatic, many people are unaware that they are carrying the virus and able to transmit it to others before they become ill.

NIDA has been actively participating on the PHS Executive Task Force on AIDS and has membership on the various subcommittees of the task force. We have participated in numerous Congressional hearings on the topic and have responded to a ground-swell of requests for technical assistance. To assure that a coordinated and meaningful program is initiated, an AIDS Task Force has been established out of the Office of the NIDA Director. It is charged with coordinating activities, monitoring the progress of the overall effort and preparing consistent and coherent reports on NIDA's research and prevention initiatives. In addition, a new section is being established in the Division of Clinical Research to launch an aggressive clinical research program into the area. A grant announcement has recently been issued to stimulate more research in this area.

A major goal of this research program will be to clarify the epidemiology and natural history of AIDS in relation to IV drug abuse. While it now appears evident that the [illegible] among IV drug users is primarily due to the sharing of needles, there are a number of questions about the nature of the virus and host response and the role of drug use in the development of the disease. It has been noted that AIDS victims who are IV drug users present with different diseases and tend to die in a shorter period from AIDS than victims without a history of IV drug use. This suggests that, while the initial transmission of the virus in these users may be due to needle sharing, the subsequent course of the disease may be influenced by drug use. There are also animal data which have suggested that drugs may compromise immune functioning. Studies underway in this area will be expanded to determine if drug use may increase the risk of contracting AIDS or affect the severity of the disease once it is contracted.

AIDS Prevention

NIDA's efforts in AIDS prevention are geared to the reduction of [illegible] associated with AIDS among IV drug users. Current efforts are focused on [illegible] including the [illegible] community, health care professionals, other medical/health personnel and other professionals who come into contact with intravenous drug users to conduct AIDS prevention programs, early diagnosis and treat AIDS patients; and the development of effective prevention strategies to reduce intravenous drug use.

Efforts to better inform professionals who come into contact with IV drug users on how to prevent and treat AIDS include the development of training manuals and audiovisual materials explaining the relationship between IV drug use and AIDS and how to diagnose and treat AIDS patients, sponsorship of workshops, and the provision of technical assistance to State and local organizations. Efforts to develop better prevention materials are especially important because of the particularly high rate of transmission of AIDS between IV drug users and their relatively high resistance to normal prevention materials. [illegible] allocation of additional funds.

such as targeting prevention messages toward the families or sexual partners of IV drug users, in attempting to improve the effectiveness of prevention programs.

In 1987, workshops will be conducted for persons associated with drug abuse service delivery, criminal justice administration, and health care to improve their understanding of HTLV-III testing, counseling of AIDS patients, and assiting AIDS patients in the health care system. Efforts will also be made to provide information on the precautions and strategies to be employed in working with HTLV-III positive patients in both residential and outpatient programs. NIDA will also work with national organizations representing State drug abuse agencies and local drug abuse treatment programs to assist in the development of policies at the State and local levels.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

REPORT ON ACTIVITIES IN
AGING

A REPORT TO THE
HOUSE COMMITTEE ON APPROPRIATIONS
JANUARY, 1986

DEPARTMENT OF HEALTH AND HUMAN SERVICES
ACTIVITIES SERVING OLDER AMERICANS
DURING 1985

In response to the many social, health, economic, and other needs of the Nation's elderly, a wide range of programs serving this age group were administered during FY 1984 by various agencies throughout the Department of Health and Human Services (DHHS). This report begins with a tabular summary of actual and expected annual expenditures for HHS activities on behalf of older Americans by each HHS agency performing them. Narrative descriptions of those activities, as listed below, follow.

I. Office of Human Development Services

   A. Administration on Aging

   B. Administration for Native Americans

II. Public Health Service

   A. Office of the Assistant Secretary for Health

   B. Health Resources and Services Administration

   C. Alcohol, Drug Abuse, and Mental Health Administration

   D. National Institute of Health

III. Health Care Financing Administration

IV. Social Security Administration

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Funds for Programs on Aging
(in thousands of dollars) 1/

	1983	1984	1985	1986 Enacted	1986 After Sequester	1986 2/ Current Request	1987 3/ Request
I. Office of Human Development Services							
A. Administration on Aging, Title II National Clearinghouse on Aging	-0-	-0-	-0-	-0-	-0-	-0-	-0-
Title II, Federal Council on Aging	135	135	200	200	191	191	200
Title III, Planning, Coordination, Evaluation and Administration of State Plans	21,673	21,673	4/	4/	4/	4/	4/
Title III-B, Social Services	$240,669	$250,669	$265,000	$265,000	$253,605	$253,605	$265,000
Title III, Part C, Subpart 1 Congregate Nutrition Services	319,074	321,576	336,000	336,000	321,552	321,552	336,000
Title III, Part C, Subpart 2, Home Delivered Nutrition Services	62,025	63,025	67,000	67,000	64,980	64,980	67,000

1/ All amounts in this tabulation are stated in thousands of dollars, except those relating to Social Security Administration and Health Care Financing Administration programs, which are stated in millions.

2/ Excludes Gramm-Rudman-Hollings reduction and proposed recission.

3/ All figures in this column are estimates, based upon 1987 Budget requests.

4/ The 1984 amendments to the Older Americans Act eliminated separate funding for planning, Coordination, Evaluation and Administration of State Plans and permit States to use funds allotted under Part B and C for these activities.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Funds for Programs on Aging
(in thousands of dollars) 1/

	1983	1984	1985	1986 Enacted	1986 After Sequester	1986 2/ Current Request	1987 3/ Request
II. Office of Human Development Services (cont.)							
A. Administration on Aging (cont.)							
Title IV, Training Research and Discretionary Projects and Programs	$22,175	$22,175	$25,000	$25,000	$23,925	$12,500	$12,500
Title VI, Direct Indian Grants	5,735	5,735	7,500	7,500	7,178	7,178	7,500
B. Administration for Native Americans	4	---	-0-	-0-	---	---	---

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1/ All amounts in this tabulation are stated in thousands of dollars, except those relating to Social Security Administration and Health Care Financing Administration programs, which are stated in millions.

2/ Excludes Gramm-Rudman_Hollings reduction and proposed recission.

3/ All figures in this column are estimates, based upon 1987 Budget requests.

4/ The 1984 amendments to the Older Americans Act eliminated separate funding for planning, Coordination, Evaluation and Administration of State Plans and permit States to use funds allotted under Part B and C for these activities.

II. PUBLIC HEALTH SERVICES

A. OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

LONG TERM CARE

OBLIGATIONS

	1983 Actual	1984 Actual	1985 Actual	1986 Estimate	1986 Estimate After Sequest.	1987 Estimate
Public Health Service:						
A. Office of the Assistant Secretary for Health:						
1. National Center for Health Services Research and Health Care Technology Assesment:						
Grants and Contracts.......	$680,305	$593,282	$1,222,953	$686,065	$586,065	$551,088
TOTAL.................	$680,305	$593,282	$1,222,953	$686,065	$586,065	$551,088

AGING

	1983 Actual	1984 Actual	1985 Actual	1986 Appropriation	1986 after Sequestering	1986 Revised Estimate	1987 Estimate
	Obligations						
II. Public Health Service:							
B. Health Resources & Services Administration:							
Bureau of Health Professions							
Nursing Special Projects......	$ 183,721	$ 417,230	$ 300,000	$ 330,000	$ 315,000	$307,724	--
Nurse Practitioners.	1,358,993	1,498,358	1,511,400	1,500,000	1,432,500	--	--
Advanced Nurse Training.....	1,261,515	1,079,081	1,338,060	1,300,000	1,241,500	77,566	--
Nursing Research Grant Project..	80,248	1,260,966	715,737	750,000	716,250	--	--
H.P. Special Educational Initiatives (Sec. 788(b-e))	871,714	996,371	6,100,000	5,000,000	4,785,000	--	--
Area Health Education Centers.......	1,866,086	1,539,240	1,132,786	1,132,786	1,004,076	--	--
Physicians Assistants....	37,388	39,300	69,074	69,074	66,106	--	--
Family Medicine Residencies..	1,743,811	1,795,581	1,765,188	1,765,188	1,689,285	--	--
Family Medicine Departments..	132,174	--	73,903	73,903[1]	70,725	--	--
General Internal Medicine and Pediatric Residencies...	16,107	102,958	183,677	183,677	175,779	6,060	--
H.P. Analytical Studies and Reports (Dental).....	49,887	--	--	--	--	--	--
Program Support........	--	120,481	--	--	--	--	--
Total.......	$7,616,361	$9,047,783	$13,209,815	$12,124,628	$11,516,219	$391,350	--

C. ALCOHOL, DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION

Obligations for Programs on Aging

1983	1984	1985	1986 Appropriation	1986 Available after Sequestering	1986 Revised Estimate	1987
$13,823,000	$17,876,000	$21,111,000	$22,472,000	$21,564,000	$15,423,000	$15,493,000

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Funds for Program on Aging
(in thousands of dollars)

II. Public Health Service (cont.)	1983	1984	1985	1986 Approp.	1986 after Sequester	1986 Current Estimate 1/	1987
D. National Institutes of Health							
National Institute on Aging..............	$93,946	$115,216	$142,968	$157,675	$150,946	$148,267	$145,829
National Cancer Institute..............	12,042	12,862	15,034	17,000	16,300	14,000	13,000
National Heart, Lung and Blood Institute....	2,920	3,751	7,988	8,500	8,135	8,000	7,800
National Institute of Diabetes and Digestive and Kidney Diseases....	173	568	689	720	690	680	670
National Institute of Neurological and Communicative Disorders and Stroke............	12,815	17,098	18,566	20,309	19,436	18,988	18,787
National Institute of Allergy and Infectious Diseases..............	16,194	18,394	20,812	21,479	20,548	20,444	19,854
National Eye Institute	22,314	23,115	27,625	30,100	28,800	27,900	27,800
National Institute of Arthritis and Musculoskeletal and Skin Diseases..........	534	813	968	1,030	985	970	950
Division of Research Resources.............	3,496	3,310	4,617	4,621	4,442	4,442	3,880
Total, NIH......................	164,634	195,129	239,267	261,434	250,282	243,691	238,570

1/ Excludes Gramm-Rudman-Hollings reduction of $11,152,000 and proposed rescission of $6,591,000.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
III. Health Care Finance Administration

Funds for Programs re Aging
(in millions of dollars)

	1983	1984	1986 1985	1986 After Enacted	1986 2/ Current Sequester	1987 3/ Request	Request
Medicaid	6,709	7,340	8,057	8,878	8,878	8,878	9,590
Hospital Insurance Benefits	33,707	36,733	42,432	43,219	43,015	43,015	45,1791
Supplemental Medical Benefits	14,726	16,563	18,591	20,918	20,858	20,858	23,341

Medicaid is exempt from Gramm-Rudman-Hollings reduction.

I. OFFICE OF HUMAN DEVELOPMENT SERVICES

A. ADMINISTRATION ON AGING

Title II of the Older Americans Act of 1965 established the Administration on Aging as the principal Federal agency for carrying out its provisions which attempt to remove barriers to economic and personal independence for older persons and assure the availability of appropriate services for those in the greatest social or economic need. The provisions of the Act are implemented primarily through the establishment of a national "network on aging" consisting of the Administration on Aging at the Federal level, State Units and Area Agencies on Aging established under Title III of the Act, and the agencies and organizations providing direct services at the community level. In FY 1985, Congress appropriated $701,400,000 to support programs and activities to implement the provisions of the Act, which are administered by AoA. [This excludes $200,000 available for the Federal Council on Aging under the Older Americans Act appropriation.]

1. Role and Function of AoA

The Administration on Aging (AoA) is located in the Department of Health and Human Services (DHHS). Title II of the Older Americans Act describes the basic roles and functions of AoA. Chief among these are to administer the programs authorized by Congress under Titles III, IV, and VI of the Act, and to serve as an effective and visible advocate for older persons within the Department and with other agencies and organizations.

The AoA Regional Offices provide direction and guidance to the State Units on Aging funded under Title III. They assist Governors and other State officials with planning and program implementation, approve Title III State plans, and monitor the collection of Title III performance data. Regional Offices also administer selected discretionary grants authorized under Title IV.

AoA provides advice, assistance and consultation to the Assistant Secretary for Human Development Services, the Secretary of Health and Human Services, other Federal agencies, and to Congress on the characteristics, circumstances, and needs of older persons. The Agency also reviews and comments on departmental policies and regulations concerning services which affect the health and general well-being of older persons.

2. Leadership and Advocacy Activities

A major responsibility of the Administration on Aging is to provide leadership to other Federal agencies and the national network on aging relative to their efforts on behalf of the elderly. Toward this end, AoA has developed and implemented a variety of special initiatives aimed at improving the quality of life for older persons. Examples of special initiatives undertaken during FY 1985 are described below.

- Health Promotion Initiative - AoA and the Public Health Service (PHS) have jointly undertaken a multi-year effort to encourage States and local communities to develop health promotion activities for older Americans. The strategy of the joint AoA/PHS Health Promotion Initiative is to facilitate collaboration between State and local health departments, State and Area Agencies on Aging, and appropriate voluntary organizations at the local level. AoA and PHS provide both the leadership for this effort and written materials for use in designing and implementing local programs.

  All States and jurisdictions now have designated lead State agencies. By the end of FY 1985, thirty-eight State agencies had established State-level coalitions. Four State Agencies on Aging, in conjunction with private sector organizations, applied for funds for health promotion activities under AoA's State/Private Sector Initiative. The focus of these activities has been in the areas of nutrition, exercise and physical fitness, and drug management (see section on State Agency/Private Sector Initiative).

  The Aging Health Policy Center at the University of California at San Francisco completed four documents: Directory of Health Promotion Programs, Resource Guide to Nutrition, Resource Guide to Injury Control, and Resource Guide to Drug Management. These documents will be printed and disseminated in FY 1986 Six thousand packages of two publications developed by the Aging Health Policy Center, Strategies for Action (Process Guide) and Annotated Bibliography, were printed and distributed.

- The Sixth Commissioner's Forum on Aging was held in Dallas, Texas on December 10, 1984. The theme of the Forum was "Health: Nutrition and Wellness--Make It Last a Life Time." Over 500 attendees participated in workshops on ways to improve the coordination of nutrition and supportive services; involving the private sector food industry; kitchen sanitation; chemicals in foods; physical fitness and nutrition; prevention and community care; and future directions.

- Alzheimer's Disease Initiative - In FY 1984, AoA implemented a multi-year special initiative for the development of support groups for families of older persons with Alzheimer's disease. AoA Regional Offices and the Long-Term Care Gerontology Centers trained State Unit and Area Agency personnel about Alzheimer's disease and the development of community-based support groups. Subsequently, State Units and Area Agencies have been asked to replicate this training. A comprehensive technical assistance package was developed and, nearly 10,000 copies of this material have been distributed nationwide.

  More than 5,000 persons who work with older persons have now been trained. Forty-one (41) States have made a commitment to undertake significant State activity to support this effort. Twelve States have formed State level task forces to develop recommendations for changes in State programs and to improve services to older persons with Alzheimer's Disease and their families. Seven of these States have appropriated State funds to support new activities such as day care, respite care, and other such services. Many States have instituted ongoing training programs to help staff understand the needs of Alzheimer's patients.

  Another significant undertaking in support of AoA's Alzheimer's Disease Initiative was the funding in FY 1985 of twelve (12) research and demonstration projects aimed at: 1) increasing public awareness and understanding of the disease; 2) demonstrating and testing models for family support groups, particularly in rural areas; and 3) developing innovative approaches to respite care and caregiver training.

- Housing Initiative - During FY 1985, AoA continued one and initiated two other major activities under its multi-year initiative to improve the housing and living arrangements of older persons. The activity, continued from FY 1984, concentrated on home weatherization, safety and security. The first effort initiated during FY 1985 concentrated on home equity conversion and the second on alternative living arrangements. The home weatherization, safety and security effort involved the continued conduct of on-going projects and the implementation of new volunteer-assisted projects.

  The major thrust of this initiative was to mobilize communities to address housing problems at the local level. Activities were also carried out at the national level. These included AoA cooperation with the U. S. Consumer Product Safety Commission (CPSC) to develop and test the "Home Safety Checklist for Older Consumers." AoA supported the printing of 1,000,000 copies of the checklist and disseminated them to Area Agencies on Aging.

  During FY 1985, 28 State and 343 Area Agencies on Aging implemented activities in the area of home weatherization, safety and security.

  The second housing activity was designed to enhance the capacity of State and Area Agencies on Aging to work with private sector organizations to make home equity conversion options more available to older people. During FY 1985, AoA carried out major activities designed to provide information about the potential impact of home equity conversion on older people. At the national level these activities included co-sponsoring "The Future is Now: A Home Equity Conversion Conference," with the U.S. Department of Housing and Urban Development and the Federal Council on Aging.

  At the State and local level, workshops were conducted by 23 State Agencies on Aging to educate public and private providers of services to older people about home equity conversion and its potential to generate additional income for some older people. Revision of laws, ordinances and policies that impact home equity conversion were made or influenced by 37 State and 58 Area Agencies on Aging.

The third AoA housing activity was designed to enhance the capacity of State Units and Area Agencies on Aging to provide information about alternative housing and living arrangements and thereby increase the options available to older people. At the State and local level, workshops were conducted by 33 State Agencies on Aging to educate public and private providers of services to the elderly about alternative living arrangements for older people. Revision of laws, ordinances and policies to promote alternative living arrangements were made or influenced by 26 State Units and 113 Area Agencies on Aging.

o Energy Initiative - The goal of AoA's efforts in the energy area is to assist older persons to cope with high energy costs, to educate the public about prevention of energy-related illness in older people, and to help resolve other energy related concerns that affect older persons now and in the future. As a member of the Aging and Energy Consortium Steering Committee and as Co-Chair of its Project Committee, AoA has worked to encourage the development of State energy and aging consortia which focus on the energy needs of older persons. AoA has encouraged States to develop public/private partnerships using the Consortium model and AoA and American Gas Association staff developed a manual on how to develop a State Energy and Aging Consortium.

AoA also provided financial and staff support to the National Energy and Aging Consortium for a conference entitled "Building Partnerships for the Future of Our Aging Society." In September, 1985, AoA in cooperation with the U.S. Department of Energy, sponsored a symposium on our nation's energy supply and its availability to older persons in the 21st century.

Lastly, through a grant to the Center for Environmental Physiology, technical assistance materials on hypothermia were distributed to 140 health and public safety organizations.

o Older Americans Month Celebration - The theme for the May 1985 celebration of Older Americans Month was "Independence." The goals around this theme were intended to educate older Americans, their families, neighbors, community groups, and business and industry to ways that they could foster and enhance the elderly's independence. As a part of the Older Americans Month campaign, AoA invited the State Units on Aging to select an exemplary project in each State for a Project Independence Award. Forty (40) projects were selected, and recipients attended a ceremony in Washington, D.C. to honor the contributions of the individual projects as well as the 20th anniversary of the Older Americans Act.

Last year, AoA was joined at the national level in its Older Americans Month celebration by the private sector. Morrison's, one of the largest food service corporations in the United States, printed and distributed the OAM poster, prepared the Project Independence Awards plaques, and hosted the luncheon reception for more than 250 people held immediately following the ceremony.

o Commissioner's Planning Initiative - In June 1985, AoA completed the development of a forward plan of program activities for fiscal years 1986-1988. This plan includes seven major objectives dealing with issues critical to the current and future well-being of older Americans. The objectives reflect areas in which AoA currently provides direct leadership as well as areas in which the agency can serve as a catalyst in bringing about heightened awareness of, and preparation for, meeting the needs of the elderly.

There are key elements and activities in this plan that are designed to increase family and individual self-sufficiency; to target assistance on those elderly most in need; to improve the effectiveness and efficiency of State and locally administered social services; and, to improve the effectiveness and efficiency of AoA internal operations. An important component of AoA's forward plan is the provision of individualized assistance to State Units on Aging on specific projects identified by the States as priorities for action. This forward plan also has been an important basis in formulating and developing the Agency's operational, evaluation and discretionary plans.

3. Title III Supportive and Nutrition Services

Under Title III of the Older Americans Act, the Administration on Aging provides financial assistance to the States to develop greater capacity and foster the development of comprehensive and coordinated service systems to serve older individuals.

The law requires the designation of an agency within each State to be specifically responsible for carrying out the purpose of the Act. The State Unit on Aging is required to subdivide the State into Planning and Service Areas (PSA) and to designate for each PSA an Area Agency on Aging (AAA). Funds are made available to the States upon approval of State plans by AoA Regional Offices. States then allocate funds to Area Agencies based upon approved area plans. Funds provided to Area Agencies are used for the administration and support of a wide range of community-based supportive and nutrition services authorized under Parts B and C of Title III. The 1984 Amendments to the Older Americans Act (P.L. 98-459) eliminated the separate allotment for Part A (State Administration), and provided States with the option of using a portion of the funds allotted under Parts B and C of Title III to support State Unit administrative and advocacy activities. Therefore, in FY 1985, three separate allocations were made to States for: (a) supportive services and senior center operations; (b) congregate nutrition services; and (c) home-delivered meals. Under the Older Americans Act, the State Units have the authority to transfer limited amounts of funds among the three Title III allotments in order to better reflect their local needs and priorities. In FY 1985 the net transfers were:

Title III-B (Supportive Services)	+$ 21,439,681	+ 8.1%*
Title III-C-1 (Congregate Nutrition Services)	-$ 46,477,250	- 13.9%*
Title III-C-2 (Home-Delivered Nutrition Services)	+$ 25,037,569	+ 36.9%*

As reflected in the figures above, States have made considerable use of the flexibility permitted them under the law. They elected to transfer approximately $46.2 million out of their congregate nutrition programs in order to increase their levels of investment in supportive services and home-delivered nutrition services.

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* Transfers as a percent of original allotments.

The States make awards to the Area Agencies, based upon their approved area plans, to pay up to 85 percent of the costs of supportive services, senior centers and for nutrition services. At the State and local level, the State Units and Area Agencies are charged with performing roles of advocacy and coordination similar to the responsibilities of AoA at the national level.

As already indicated, the general purpose of the Title III program is to develop greater capacity at the State and local levels and foster the development of comprehensive and coordinated service systems to serve older persons. The Title III program has evolved from a relatively simple program of over 1,500 community service projects for older persons administered by 57 State Units on Aging into a complex and highly differentiated "national network on aging" currently consisting of 57 State Units and 670 Area Agencies on Aging and more than 26,000 local nutrition and supportive service providers. These nutrition and supportive service providers are local public, private, or voluntary organizations which deliver the direct services to older persons in their communities. Not only do the State Units and Area Agencies use Title III monies to provide services, they are also instrumental in leveraging other public and private monies (for example, other State and local funds, private foundation contributions, and other Federal funds) in supporting the needs of older persons.

In FY 1985 AoA continued implementation of initiatives to target assistance to needy groups in the elderly population, and to help State Units and Area Agencies position themselves to meet increased demands for services at a time when economic recovery depends upon restraint in Federal and State expenditures.

o Minority Participation Initiative - The Administration on Aging has launched a national initiative to assist State Units on Aging to increase minority participation in Older Americans Act programs. This initiative combined the cooperative efforts of State Units on Aging, Regional AoA Offices, and four national aging minority organizations: Asociacion Nacional Pro Personas Mayores, National Center on Black Aged, National Pacific/Asian Resources Center on Aging, and National Indian Council on Aging.

  Last year, biregional workshops on minority participation were conducted in New Mexico, Idaho, Virginia, Connecticut, and Kansas. Each State was requested to prepare a strategy to increase minority participation in that State. To further support this effort, each of the national minority organizations noted above was granted Title IV funds to carry out activities to improve minority access to services. The National Association of Area Agencies on Aging was funded by AoA to publish a technical assistance manual and also has supported the Texas Migrant Council in an information and dissemination project. In addition, Florida A and M University has been awarded funds to develop outreach strategies.

- Participant Contributions Initiative - Another initiative is intended to increase voluntary contributions from program participants. Title III regulations require that each service provider must "provide each older person [receiving services] with a full and free opportunity to contribute toward the cost of the service." Although AoA emphasizes through the aging network that this is not a fee and that contributions are entirely voluntary, these contributions have been steadily increasing, as follows:

FY 1981	$ 79.0 million
FY 1982	100.8 million
FY 1983	116.7 million
FY 1984	131.7 million
FY 1985	139.6 million

- Performance-Based Contracting Initiative

The performance-based contracting system (PBC) is an integral part of the Administration on Aging's continuing initiative for improving the State Units' and Area Agencies' financial management capability. Area Agencies using the system enter into payment agreements that have fixed prices for reimbursing service providers for mutually and commonly defined service units. Service providers are reimbursed only for the services delivered rather than their total budgeted costs. The system components move service providers toward greater accountability and cost-effectiveness in their delivery of services.

Through FY 1985, forty-three State Units on Aging have promoted PBC by providing training sessions, issues workshops, and general technical assistance on use of the system.

During FY 1985 AoA completed an evaluation of Performance-Based Contracting which is discussed in the Section on Evaluation.

- Nutrition Productivity Initiative - The nutrition productivity initiative aims to maintain or expand nutrition services while simultaneously reducing or controlling meal costs. During FY 1985 State Units and Area Agencies continued to explore and examine the various ways to maximize the production of meals and minimize the costs to the Title III program.

- Public and Private Sector Employment Initiatives - AoA continued during FY 1985 to promote the hiring and/or retention of older workers in the public and private sector workforces. For the public sector initiative, AoA established an objective to increase the proportion of older workers employed by State Units and Area Agencies by 10 percent over the levels reported in FY 1983. AoA's Private Sector Employment Initiative was designed to link private sector employers, particularly small business owners, with older persons interested in full- or part-time employment. During FY 1985, 41 State Units on Aging, 373 Area Agencies on Aging, and 10,396 private businesses participated in the private sector employment initiative.

- State Agency/Private Sector Collaboration Grants - In FY 1985, twenty-six (26) grants totalling more than $2.1 million were awarded through Administration on Aging (AoA) Regional Offices (RO's) to 24 State Units on Aging (SUA's) for the purpose of increasing collaboration between the public and private business sectors. The competition was held as part of President Reagan's Private Sector Initiative campaign launched four years ago to encourage greater involvement by private citizens and organizations in the solution of public problems.

4. State and Area Agencies on Aging

Fifty-seven States and other jurisdictions receive support under Title III of the Act. The 1981 Amendments to the Act provided greater flexibility to State Units by permitting them to elect durations of two, three or four years for State and area plans. Beginning on October 1, 1985 (FY 1986), 23 States or Territories (40 percent) operated on a two-year cycle; 26 (46 percent) operated on a three-year cycle; and 8 (14 percent) operated on a four-year cycle. State Units are organizationally located in State governments either as independent agencies reporting directly to the Governor, or as components of larger human services agencies.

State Units used Title III-B (Supportive Services) funds and funds from other sources to establish and maintain long-term care ombudsman programs at the State and sub-State levels. The 1981 Amendments to the Act required States to extend their services and protection of older persons to residents of certain types of boarding homes. Through their ombudsman programs, States have addressed such issues as nursing home regulations, abuse of residents' personal funds, and restrictions on access to nursing homes.

In FY 1985 there were 670 Area Agencies on Aging operating under Title III of the Act. As of the end of FY 1985, there were 683 Planning and Service Areas, including 13 single planning and service areas covering whole States and territories. An Area Agency on Aging may be a public or private organization, an Indian Tribe, or a sub-state regional body.

Area Agencies are responsible for providing technical assistance to, and monitoring the effectiveness and efficiency of, their respective service providers. They interact with other local public and private agencies and organizations in order to coordinate their respective activities and elicit or "leverage" additional resources to be used on behalf of older persons.

State Units on Aging and Single Planning and Service Areas received a total of $668.5 million of Title III funds during FY 1985. Of this amount, approximately 86 percent was used for supportive and nutrition services and the remainder was spent for administrative purposes. Area Agencies augmented their Title III funds through eliciting support from other Federal, State and community sources. In addition, income is generated by the program from such sources as participant contributions for meals which have been increasing steadily over the years.

5. Title III Services

Title III-B supportive services are designed to provide assistance to those older persons in need. Most supportive services fall in three broad categories: access services, in-home services, and other community and neighborhood services. Access services are transportation, outreach, and information and referral. Most in-home services are either housekeeping, personal care, chore, and visiting and telephone reassurance. Community and neighborhood services include legal service, residential repair, escort service, health services, physical fitness programs, pre-retirement and second career counseling, and other services. The Title III-B program is currently reaching an estimated nine (9) million older clients. In FY 1984, 18 percent of all participants were racial and ethnic minorities, and 47 percent were low income.

Over 147 million congregate meals were served to older people and their spouses during FY 1984. In addition to Title III funds, these meals are also supported by State funds, Social Services Block Grant and other Federal funds, State/local funds not included as part of the FY 1984 Title III requirement, and participant contributions. Over 2.9 million elderly received meals at congregate sites. During FY 1984, 66.7 million meals were provided to the homebound elderly from all funding sources. Approximately 611,000 older persons received these meals.

6. Title VI Grants to Indian Tribes

Under Title VI of the Older Americans Act the Administration on Aging annually awards grants to Federally-recognized Indian Tribes. These grants assist the Tribes in delivering nutrition and supportive services to the Tribes' elderly.

In FY 1984, there had been eighty-three (83) grants awarded, from an appropriation of $5,735,000, for an average grant award of approximately $69,000. In FY 1985, following an invitation for new Indian Tribes to apply, there were 125 grants awarded, from an increased appropriation of $7,500,000. The average grant for FY 1985 was $60,000.

The Older American Act Amendments of 1984 reduced from 75 to 60 the number of Indians age 60 years or over which a tribal organization must represent in order to be eligible to apply for a grant. This amendment will not result in additional grantees until FY 1986.

In FY 1985, the Tribes were distributed over nine of the ten DHHS regions and were in twenty-four (24) States. Louisiana was represented for the first time in FY 1985.

During FY 1985, Title VI service data were analyzed for the FY 1984 funding period. The data reflect the following:

- Of the eligible population of 18,927, 94 percent (17,730 persons) participated in nutrition services, and 69% (13,116 persons) received one or more social services.

- Of the 17,730 older Indians participating in nutrition services, 69 percent received their meals in a congregate setting and 31 percent received their meals at home.

- The supportive services provided most frequently continue to be transportation and information and referral.

- Of the 730 persons involved in paid and non-paid staff roles, more than 60 percent were volunteers.

- About 61 percent of the Tribes' total expenditures were for meals.

In May 1985, AoA invited the Title VI grantees to participate in a developmental effort to improve and expand services to older Indians. This effort provided for one-time Title IV awards to be to stimulate developmental projects for education and training (98 grants); program planning and resource development (82 grants); research, demonstration,and other studies (65 grants); program coordination (41 grants); and cooperative management(14 grants). Overall, 104 or 83 percent of the 125 Title VI grantees took advantage of the opportunity to submit applications. The Commissioner awarded Title IV grants to all the Title VI Indian Tribes that had applied.

7. AoA Discretionary Programs

a. Title IV-A--Education and Training

Section 411 of the Act authorizes the award of grants and contracts to assist in recruiting persons to enter the field of aging; in training volunteers and persons employed in or preparing for employment in the field of aging; and to provide technical assistance and other activities related to such training.

(1). Gerontology Training Program - In FY 1985, thirty-one (31) new projects were awarded grants in four competitive areas.

- Career Preparation for Employment in Aging - Support was provided to eleven academic institutions for development and improvement of educational programs for persons preparing for paraprofessional and professional careers in the field of aging.

- Continuing Education and Training - Six grants were awarded to academic institutions and professional organizations to develop gerontology or geriatric programs and materials and provide training to Network on Aging personnel.

- Allied Professions in Aging - Several grants were awarded to train professionals and paraprofessionals whose careers have a significant impact on the elderly. These awards were made to academic institutions, professional associations and other organizations.

- Minority Training and Development in Gerontology - A number of grants were awarded to institutions of higher education with a large minority enrollment, including Historically Black Colleges and Universities (HBCU's), and to nonprofit organizations representing minority groups. These these awards were to improve training programs and, to support faculty and institutional development. Awards were made to other minority institutions for multidisciplinary development in gerontological training.

(2). Regional Office Developmental Activities - Activities supported by Title IV funds were initiated in FY 1985 to assist the ten AoA Regional Offices in the effective implementation of national and regional priority program initiatives, such as health promotion, housing, long-term care, employment, Alzheimer's Disease (including respite care and family support systems), nutrition, and other special initiatives.

(3). Title VI Developmental Activities

During FY 1985, the Administration on Aging awarded funds to Indian Tribes currently administering Title VI grants to conduct developmental activities. These activities are described in the Title VI Section of this report.

(4). State Older Adult Literacy Grants

In FY 1985, grants totalling more than $870,000 were awarded to 20 State Units on Aging to promote literacy opportunities for older persons. Projects focus on the recruitment and training of older illiterates, recruitment and training of older volunteers, education of literacy provider agencies on the needs of older persons, and public awareness campaigns to increase understanding of older persons literacy needs.

b. Multidisciplinary Centers of Gerontology

Title IV-A, Section 412 of the Act, authorizes the award of grants to public and private nonprofit agencies, organizations, and institutions for the purpose of establishing or supporting multidisciplinary centers of gerontology, and gerontology centers of special emphasis, such as long-term care.

(1). National Policy Studies Centers

In FY 1985, AoA continued funding for three National Policy Studies Centers in the areas of income maintenance, health, and employment, which were originally funded in FY 1980. During the past year the Centers were engaged in policy analysis and development; policy research; and the preparation of personnel for undertaking work in these areas and for teaching these skills to others. Two of these National Policy Studies Centers -- the Policy Center on Health at the University of California at San Francisco and the Policy Center on Employment and Retirement at the University of Southern California --completed their work for AoA during FY 1985. A third Policy Center on Income Maintenance at Brandeis University will complete its work during FY 1986.

(2). Long-Term Care Gerontology Centers

In FY 1985, the Long-Term Care Gerontology Centers were also funded under Title IV-A, Section 412. The Centers are discussed in the Long-Term Care section of this report.

c. Title IV--B Research and Demonstrations Projects

Title IV-B, Sections 421, 422, 424, and 425 of the Older Americans Act authorizes funding for projects to identify, assess, and demonstrate new approaches and methods to improve the well-being and independence of older persons. The primary objective of AoA-supported research is to develop new knowledge that will increase the capacity of State and local agencies, in both the public and private sectors, to assist older persons in achieving and maintaining economic and personal independence. AoA-funded demonstration projects seek to test new models, systems, and approaches for providing and delivering services.

In FY 1985, AoA targeted most of its research and demonstration efforts on twelve (12) program areas of priority interest and concern to the elderly. These priority areas and projects are:

(1). Consumer-Directed Preventive Services - AoA funded eight projects to promote effective use of both the public and the individual's resources to ensure the availability of community services when needed. These projects will produce models of preventive consumer-directed life service plans.

(2). Alzheimer Disease Support Network - AoA made twelve new awards to projects designed to find more effective ways of serving Alzheimer's Disease victims and their families. These research efforts paralleled the HHS priority to find the cause of and the cure for Alzheimer's Disease.

(3). Housing - AoA granted fifteen new awards in FY 1985 to improve housing and living arrangements for the elderly. Eleven were made to demonstrate effective techniques for conveying information on housing options to older persons. Two projects were funded to foster public and private collaboration at State and local levels to address the housing and living arrangements of older persons. Another project will disseminate free safety knowledge through a series of workshops.

(4). Employment - Four new projects were funded in FY 1985 to demonstrate ways to increase the economic self-sufficiency and employment opportunities of the elderly. Three focus on job match systems and placement models; a fourth will produce a documentary film to persuade employers to hire, train, and retain older workers.

(5). Legal Services and Assistance - Four projects were funded, including grants to national legal assistance organizations, to improve the provision of legal services for the elderly.

(6). Elder Abuse - AoA made two new awards to disseminate available knowledge in this field. One project brings together academic expertise with organizations representing State Agencies on Aging and State social services agencies in a collaborative effort to transfer knowledge about elder abuse to service planners, administrators, practitioners, educators, and researchers. The other will replicate at four new sites a successful city-wide provider consortium model of elder abuse prevention and intervention.

(7). Voluntarism - Three awards were made to demonstrate models that can be used by social service agencies to maximize the impact of corporate contributions. For example, these awards will enlist the corporate sector in recruiting employees and retirees as volunteers to serve the chronically impaired elderly; and will broker the services of retired executives and professionals to help solve the management problems of aging services organizations.

(8). Informal Caregiving - Seven awards made in FY 1985 focus on informal caregivers. Four identify and analyze data and disseminate information about model support groups for family caregivers; three explore such issues as how the provisions of the tax code can be used to extend corporate programs for employee benefits for dependent care to include the care of elderly parents.

(9). Intergenerational Programs - Four awards were made to demonstrate the advantages of utilizing an intergenerational approach to promote health and cultural enrichment for Indian elders and Indian children. AoA also awarded a grant to a foundation to work with AoA and with other foundations to develop intergenerational projects to serve low income persons.

(10). Minority Aging Populations - Eight projects were funded in FY 1985 to address the needs of minority aging populations through innovative approaches. They will focus on housing, health, and employment for rural Black elderly persons, develop strategies to provide greater access to service programs by older Pacific/Asians and by elderly Indians, and identify long term care needs of Hispanic elderly in selected States.

(11). Improved Management of Aging Programs - Six grants were awarded to improve the program management of State and Area Agencies on Aging through the effective use of information systems. For example, several projects will assist State Units on Aging to locate and adapt or develop computer applications to support service planning and management and resource allocation.

(12). Nutrition - In FY 1985, AoA awarded a grant to promote effective new food technology for providing home-delivered meals. This project will develop and demonstrate automobile-transportable meal-heating equipment compatible with present delivery systems of the Meals-on-Wheels program for the home-based frail elderly.

d. Long-Term Care

(1). Long Term Care Gerontology Centers - During the last seven years, the Administration on Aging (AoA) provided financial support to 11 major universities across the country for the establishment of multidisciplinary long term care gerontology centers. The goal of this effort is the development of a comprehensive knowledge base about long term care issues and concerns and the establishment of interdisciplinary geriatrics/gerontology curriculum for physicians, nurses, social workers and other allied health professionals.

Since 1979, the eleven Centers have received approximately $18 million in grants from AoA. Funding for nine centers ended on September 29, 1985, completing AoA's financial commitment. The Centers also generated approximately $24 million of other resources from universities, State funds, corporate and private resources. These nine Centers have now become self-supporting and are continuing with their work in long term care. Two additional Centers at the Universities of Utah and Texas were funded by AoA in 1982 and continue to receive AoA grant funds.

Each of the Centers has developed authoritative topical expertise in the areas of Alzheimer's Disease, assessment and case management, demographic forecasting, financing mechanisms, manpower issues, technology, information systems, as well as other subject areas. The Centers have disseminated a vast array of long term care information through the development of technical assistance documents, journal articles, books, public presentations, periodic newletters, and other forms of media activities.

(2). National Long-Term Care Channeling Demonstration - The purpose of the Long-Term Care Channeling Demonstration Program was to develop community-based organizational structures and operating procedures to match resources with identified needs for continuing care of the elderly. The demonstration was jointly funded by AoA and the Health Care Financing Administration, and administered by the Office of the Assistant Secretary for Planning and Evaluation. Two different models for linking older persons with appropriate types of long-term care in the community were tested: a "basic case management" model and a more complex "financial control" model. Ten demonstration projects were divided into three phases over the period of September, 1980 through March, 1985, when project phase out was completed. States and their local channeling sites developed plans for the orderly close down of the demonstrations and the smooth transition of clients to other services in the community. At the present time the evaluation contractor is developing the final reports. A final Summary Report is scheduled for submission in the Spring of 1986.

(3). Long Term Care Research and Demonstration Projects - Two long-term care projects were completed in FY 1985. One project related to informal support systems for the frail elderly and the role of families in providing personal care. A major product of this project is the technical assistance manual entitled: "Family Seminars for Care Giving: Helping Families Help."

The second project completed in FY 1985 produced a catalog of available products with relevance to long term care resulting from AoA discretionary grant-funded projects from 1976 to 1983. Entitled: "Products of AoA Discretionary Grants in Long-Term Care: 1976-1983," it was disseminated to State and Area Agencies on Aging.

B. Evaluation

Section 206 of the Older Americans Act authorizes evaluation of the impact of all programs funded under the Act, including their effectiveness in achieving stated goals. AoA's evaluation program in FY 1985 included the completion of two projects funded in FY 1984.

- Evaluation of Performance-Based Contracting: This project was a two-phase study designed to identify those factors which may act as barriers or disincentives for Area Agencies on Aging in implementing performance-based contracting and to determine how these constraints have been overcome by Area Agencies on Aging who are currently utilizing such contract practices.

  Findings from the evaluation showed that almost all AAA's purchase some services through either cost-reimbursement or performance-based contracting. The real and perceived barriers of PBC as identified in the study are:

  - resistance from providers
  - inadequate knowledge of AAA staff
  - insufficient staff resources
  - additional monitoring requirements
  - variability of reimbursement amounts
  - lack of sophistication of provider agency
  - insufficient number of providers
  - too much paperwork
  - policymakers oppose PBC
  - PBC is inappropriate for certain services

The results of this project are providing information to AoA regarding practical technical assistance strategies and potential management initiatives which have promise of facilitating greater use of performance-based contracting practices within the aging network.

- Assessment of the Feasibility of Evaluating Substate Long-Term Care Ombudsman Programs and Development of an Instrument for the Evaluation of Effectiveness and Impact. This evaluation had two objectives. The first was to determine if sub-state and centralized long-term care ombudsman programs could and should be evaluated and, if so, to design and test an evaluation instrument and users' guide to be issued by AoA as a chapter in the Ombudsman Technical Assistance Manual. The conclusion was that programmatic diversity within and across States notwithstanding, sub-state and centralized ombudsman programs, are evaluable. An instrument and users' guide have been developed and field tested. The final instrument, users' guide, and report will be completed during the first quarter of FY 1986.

B. ADMINISTRATION FOR NATIVE AMERICANS

Cooperative Management Initiative (CMI)

In May, 1981, the Human Development Services Cooperative Management initiative was established to improve the management of Human Development Services; Indian Programs. Three program offices in the Office of Human Development Services offices are included in this initiative: The Administration for Native Americans social and economic development projects; the Administration for Children, Youth and Families' Indian Head Start programs; and the Administration on Aging's Title VI social and nutritional services programs.

The purpose of the CMI is to promote increased Tribal control over Federal Indian programs and to improve program management through a more efficient use of resources.

Six Tribes formed the pilot group which implemented the program. As a result, on April 22, 1983, an invitation was extended to all Tribes with two or more of the Human Development Services projects noted above to participate in the CMI. Approved project activities do not change if a Tribe elects to participate in CMI. Rather, CMI provides the Tribes with the flexibility to cooperatively manage projects so that scarce program resources can be more efficiently used. As of this date, ten Indian Tribes are participating in the CMI effort.

Indian Elder's Initiative

In fiscal year 1982 the Intra-Departmental Council on Indian Affairs coordinated the development of a memorandum of agreement between the Administration on Aging, Administration for Developmental Disabilities and the Administration for Native Americans. The agreement was signed by the three Commissioners on October 5, 1982. The purposes of this initiative are to: improve coordination of program efforts that enhance or extend services to more individuals without an increase in cost to individual agencies; and effect measurable, positive impact on income security, health care, and access to services for Indian older persons. Work plans have been developed by each program office in FY 1984 in response to the agreement. The Administration for Children, Youth and Families (ACYF) is a participant in the initiative and a major component involving ACYF includes the focus on those intergenerational activities jointly shared by Head Start children and the Indian elderly.

- Assessment of the Feasibility of Evaluating Substate Long-Term Care Ombudsman Programs and Development of an Instrument for the Evaluation of Effectiveness and Impact: This evaluation had two objectives. The first was to determine if sub-state and centralized long-term care ombudsman programs could and should be evaluated and, if so, to design and test an evaluation instrument and users' guide to be issued by AoA as a chapter in the Ombudsman Technical Assistance Manual. The conclusion was that programmatic diversity within and across States notwithstanding, sub-state and centralized ombudsman programs, are evaluable. An instrument and users' guide have been developed and field tested. The final instrument, users' guide, and report will be completed during the first quarter of FY 1986.

II. PUBLIC HEALTH SERVICE

A. OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

1. THE NATIONAL CENTER FOR HEALTH SERVICES RESEARCH

Long Term Care

The National Center for Health Services Research and Health Care Technology Assessment (NCHSR) seeks to create new knowledge and better understanding of the processes by which health services are made available and how they may be provided more efficiently, more effectively, and at lower cost.

NCHSR is the primary source of Federal support for research on problems related to the quality and delivery of health services. NCHSR responds to the need for better data and information, new techniques, and innovative methods for improving health care delivery. NCHSR programs evaluate health services, assess technologies, and improve access to new scientific and technical information for research users. NCHSR's research is targeted to the needs of health care policymakers, including executive and legislative officials at Federal, State, and local levels; those who operate hospitals and other health care institutions; and individuals who are responsible for health care expenditures.

The NCHSR extramural research program provides support for investigator-initiated projects in health services research conducted at universities; nonprofit organizations in institutions such as teaching hospitals; and by industry. The intramural research program conducts studies that have immediate as well as long-term implications.

DIVISION OF INTRAMURAL RESEARCH

LONG-TERM CARE PROJECT

The Division of Intramural Research's long-term care project is conducting research on the financing and delivery of long-term care. Survey data collected by NCHSR are being compared to responses from an American Association of Retired Persons (AARP) survey to assess consumer interest in purchasing insurance for long-term care. Demand models are being estimated to help assess the market for such insurance. Other data requirements for developing long-term care insurance also have been examined and existing data sets are being explored for their usefulness in identifying the feasibility and implications of alternative benefit packages. Longitudinal data from a study of San Diego nursing homes have been used to examine the effect of [illegible] admissions on length of stay. These data are also being used to explore the clinical course of nursing home patients over time.

The San Diego data are from a recently completed research experiment to test the effectiveness of case-mix incentive payments to encourage more appropriate use of nursing homes, better outcomes in nursing home patients, and reductions of hospital backup. The study found that the tested reimbursement system did improve access for heavily dependent Medicaid patients but did not affect patient care outcomes. Secondary analysis of these data will further clarify considerations for successful implementation of nursing home case-mix reimbursement.

Research is also being undertaken to determine the feasibility of modeling the major elements of the long-term care system at the state and local level. The goal is to establish a flexible framework that can be used to assess the consequences of alternative strategies for servicing the health care requirements of an aging population. Existing research and data on relevant issues will be analyzed as the initial basis for the modeling effort.

Health Services for the Aged Studies Program

The aging of the U.S. population has heightened public and private focus on the health, social, and residential services required by individuals who have lost the ability to function independently because of physical and mental impairments. The increasing risk, with age, of incurring such impairments, coupled with the rapid growth of the elderly will continue to be an important issue for public and private policies. The Health Services for the Aged Studies Program (HSASP) was initiated by NCHSR in 1985 to conduct research in three areas related to health, social and residential services for physically and mentally impaired elderly.

- Nursing Home Admission and Use
- Home and Community-Based Care
- Supply of Health, Social, and Residential Service

The HSASP completed two analyses in Fiscal Year 1985 which are of particular relevance to health policy for the elderly:

1. An analysis was completed on the private expenses for home-based long-term care for elderly with limitations in activities of daily living (ADL) and instrumental activities of daily living (IADL). Data for the study were available from the 1982 Long-Term Care Survey of noninstitutionalized elderly Americans. The study found that the amount of out-of-pocket payments expended were

associated with health status, family income and other personal characteristics of the disabled person. In addition, high amounts of out-of-pocket payments were strongly associated with "risk factors" of nursing home admission such as prior nursing home residency.

2. An analysis is being conducted on the informal caregivers of the disabled elderly residing in the community. Data from the 1982 Survey of Caregivers are being analyzed to provide a national profile of the informal caregiver network. Demographic and socioeconomic characteristics of the caregivers are being analyzed to identify who assumes the responsibility for the care of impaired elderly persons. Second, analyses to assess the level of caregiver burden is being conducted to determine the degree of emotional strain, the direct financial costs and the opportunity costs with respect to work and social responsibilities. Reports from these analyses will be available early in 1986.

In FY 1986, further analyses will be conducted on the home and community based care of noninstitutionally disabled elderly. One area will be a detailed analysis of the health characteristics of the disabled elderly, and how such characteristics predict the amount of informal and formal caregiving used. This analysis, which will use a merged file of the 1982 Long-Term Care Survey and the 1982 Survey of Caregivers, will address important factors, such as income, living arrangements, and housing characteristics.

National Health Care Expenditures Study

The National Health Care Expenditures Study (NHCES) of the Division of Intramural Research continued to conduct a number of analyses in FY 1985 which are of relevance to health policy for the elderly. Planning was begun for the 1987 National Medical Expenditure Survey (NMES), which will collect a substantial amount of new information on the elderly and long-term care. The NHCES group also published or completed a number of studies on elderly based on the 1977 National Medical Care Expenditure Survey (NMCES).

NMES will have two primary components: a household survey of 14,000 households in the civilian noninstitutionalized population and a survey of 13,000 residents of nursing and personal care homes, psychiatric hospitals and facilities for the mentally retarded.

The household survey will include an oversample of groups of particular policy interest: the elderly, blacks, Hispanics, the poor and near poor, and persons with functional limitations. In addition to the core data on use, expenditures, health insurance and sociodemographic variables, the 1987 NMES household survey will have a new focus on long term care. For example, data will be obtained on charges and sources of payment for both formal and informal caregivers and on various measures of health status and functional limitations of the noninstitutionalized long term care population.

The institutional population component will sample 700 nursing and personal care homes, 775 facilities for the mentally retarded, and 200 psychiatric hospitals. The resident sample of 13,000 patients has been designed to represent persons who were residents of such institutions on January 1, 1987 and persons who were admitted during 1987. Data will be obtained on health status and functional status; 1987 institutional charges and sources of payment; expenditures and sources of payment for care provided to sample patients by physicians, acute hospitals and other non-institutional providers during 1987; and length of stay. These data will be supplemented by information obtained from surveys of the next of kin or community respondents. Data will be obtained on the health status and functional limitations of sample patients prior to admission, characteristics of family members, and supplementary data on use, expenditures and sources of payment during 1987.

Studies published by members of the NMCES Staff in 1985 include:

> Private Health Insurance of the Medicare Population and the Baucus Legislation; Cafferata, G.L.; Medical Care, 1985.
>
> The appropriateness of the benefits associated with the private insurance coverage of the Medicare population has been the subject of considerable concern. Section 507 of the Social Security Amendments of 1980, also known as the Baucus legislation, reflects public concerns about the level of benefits in relation to premiums, duplicative coverage, the complexity and difficulty of insurance terminology, and marketing abuses. Data from NMCES provided useful baseline data on the distribution of Baucus-like plans. In 1977, private insurance held by the Medicare population was more likely to cover inpatient than outpatient services and to emphasize "first dollar" benefits for long-term care. Multivariate analyses show that the distribution of Baucus-like insurance policies is highly associated with health status, source of insurance, region, and place of residence. The importance of state regulation, suggested in other research, may account for these patterns.

The Elderly's Private Insurance Coverage of Nursing Home Care; Cafferata, G.L.; American Journal of Public Health, 1985.

About 40 percent of Medicare beneficiaries had private insurance coverage of skilled nursing facilities (SNF) in 1977. Data from NMCES show that among such persons, about 85 percent had full coverage of Medicare's Part A copayments for days 21-100 but only 15.7 percent had maximum coverage of at least 365 days of care or a benefit of $100,000 or more. The most comprehensive benefits are found among persons with middle or high incomes; more generous first-dollar coverage is found in the North Central and South regions, and more generous maximums in the West.

Use of Home Health Services: Some Findings from the National Medical Care Expenditure Survey; Berk, M.L., and Bernstein, A.B.; Home Health Care Quarterly, 1985.

Data from NMCES are used to produce national estimates of the use of and sources of payment for home health care services for various demographic groups. The findings indicate that while age and health status are strongly associated with home health care use, the majority of persons using services are neither elderly nor limited in activity. In addition it was found that private insurance is only rarely mentioned as a source of payment for home health care.

Division of Extramural Research

NCHSR's Division of Extramural Research supported a number of projects in Fiscal Year 1985 on issues related to the elderly and long-term care.

New Starts in Fiscal Year 1985 include:

"ADL Change for Elderly at Risk of Institutionalization" (Katz)

A study of Activities of Daily Living (ADL) to determine which factors are associated with a change in functional status and the relationship between this change and utilization of health services by the elderly. It is expected that the ability to predict ADL change over time would allow communities to better assess the changing mix of residents and in turn better project their service needs and the community's future financial liabilities.

"Paying Physicians for Geriatric Care" (Butler)

A consensus conference to investigate the appropriateness of third-party payment of geriatric services in primary care settings by assessing the state of knowledge, identifying issues and questions needing further study, and discussing innovative payment methods. The approach will include a survey of 50 physicians regarding their encounters with aged patients. A report of the survey will guide the final topic selection and discussion at a conference of about 60 invited participants including practitioners in geriatric care, public and private payer and third-party representatives, and administrative, legislative, and research specialists in geriatric health economics and policy.

"Consistently High and Low Elderly Users of Medical Care" (Freeborn)

An analysis of the patterns of ambulatory care use by aged members of Kaiser's (Portland, Oregon) Health Maintenance Organization (HMO) to determine what factors differentiate consistently high and low users of service. Improved understanding of these factors could lead to the design of cost containment initiatives.

"Patterns of Medical Care Utilization" (Muller)

A study to test the hypothesis that changes in the amount of own-time (defined as non-work time) due to transition from full-time work to retirement increase the use of medical services by the elderly. The study will use several waves of the Social Security Administration's Retirement History Survey. The expected findings of this study will be relevant to public policy aimed at containing government expenditures and could contribute to changes in public policy related to employment possibilities for older workers.

Projects which were on-going in Fiscal Year 1985 include:

"Outcomes of Nursing Home Discharges" (Lewis)

A study to trace and analyze the paths of care of patients discharged from nursing homes. Patients will be followed to assess utilization of health care services post discharge and to ascertain status two years following admission to the nursing home. Preliminary work has identified the movement of nursing home residents back and forth between hospitals, nursing homes, other long-term care facilities, and patients' residences as a "continuing episode of care."

This study will attempt to refine and define a measure of the "continuing episode of long-term care" which should contribute significantly to long-term care policy.

"Computer-Based System for Long-Term Care and Research" (Zielstorff)

An implementation and evaluation of Computer Stored Ambulatory Record (COSTAR) in a community-based long-term care program for a group of elderly patients at high risk for re-institutionalization. COSTAR will be implemented to link three neighborhood health care centers to a hospital-based long-term care unit. This study is intended to develop both a model program of long-term care for the elderly and specific tools to enhance the provision of care.

"Quality of Life Factors in Geriatric Medicine Decisions" (Pearlman)

A research project designed to obtain insight into the perceptions of elderly patients, their physicians, and spouses regarding the quality of the patients' lives and its role in medical decisions. This will be done by gathering data through interviewer-administered questionnaires. Physicians will be sampled from community-based practices, nursing homes, a King County (Washington) HMO, and VA medical Centers in Washington and Oregon.

"Patient Slip/Falls Evaluation and Prevention" (Jackson)

An etiologic study of slip/fall incidents in hospitals comparing an estimated population of 1000 patients experiencing slip/falls and a random group of control patients of equal size who do not slip/fall. Data will be collected from medical records, staff and patient interviews, and neurologic exams. By identifying risk factors for slip/falls, interventions can be designed and implemented to reduce these risks.

One long-term care project was completed in Fiscal Year 1985:

"Correlates of Long-Term Care Expenditures and Service" (Estes)

A study to provide an inventory of state policies relative to Federal long-term care programs and to assess the effect of these policies on availability, utilization and public cost of long-term care services; and to develop a context within which State and Federal policy choices are examined. The project's Final Report consists of a series of papers covering estimates of the effect of state discretionary policy on the expenditures and utilization associated with a particular sector of the long term care continuum. A number of policy implications are suggested concerning interprogram coordination, nursing homes, home health, and income eligibility.

State and Local User Liaison Activities

During the summer of 1986, the NCHSR User Liaison Program will sponsor the second in a series of three and one-half day workshops on long-term care for the elderly. This activity is designed to address the problems and information needs of state legislators and executive branch officials from a variety of jurisdictions. Major issues to be addressed at the workshop include: the nature and magnitude of the informal long-term care support system; projections of growth in the elderly population and its impact upon informal support and public programs; alternative arrangements for the financing and delivery of long-term care services, such as community-based service programs and Social Health Maintenance Organizations; and private long-term care insurance as a financing option. The first workshop in this series took place in June 1985.

The User Liaison Program is currently in the process of designing a synthesis of research findings pertaining to alternative approaches for the financing and delivery of non-institutional long-term care services for the elderly. This document will provide a comprehensive, objective and critical analysis of our current base of knowledge in this area as that knowledge can be applied to the concerns, problems and responsibilities of state government officials.

Ongoing consultation is provided to state and local officials with respect to information and data needs on long-term care policy and managerial responsibility.

A. OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

2. National Center for Health Statistics

AGING

All health statistics prepared by the National Center for Health Statistics (NCHS) can be presented in terms of specific age groups. Mortality data are collected through the vital statistics system and morbidity data through a number of sample surveys.

Growth in the size of the elderly population in the United States, especially during recent years, has resulted in part from decreases in mortality among the elderly. From 1940 to 1983, the death rate for the elderly decreased by 29.2 percent to 51.1 deaths per 1,000 population 65 years of age and over. In each of the five age groups 65-69 years, 70-74 years, 75-79 years, 80-84 years and 85 years of age and over, the decrease in death rates during 1940-83 was greater for females than for males.

Heart disease, cancer, stroke, and chronic obstructive pulmonary diseases accounted for three out of four deaths among the population 65 years of age and over in 1983. Inasmuch as heart disease is the leading cause of death among the elderly, mortality trends from this cause parallel the decline for all causes combined. Since 1968, death rates from stroke have been falling even more rapidly than those from heart disease. Cancer and chronic obstructive pulmonary diseases have been the only major causes of death among the elderly that have continued to show increasing death rates. The rapid increase for cancer since 1968 is primarily associated with the lung cancer increase.

Measures of morbidity among the noninstitutionalized population include the incidence of acute conditions and injuries, number of days of disability, prevalence of chronic conditions, and the number of persons whose activities are limited due to chronic conditions. The latter category is the health status measure which increases most rapidly among the elderly.

These data, from the household National Health Interview Survey (NHIS), are usually presented for the broad age groups 45-64 and 65 and older so that some other characteristics which are related to both age and health can also be shown: family income, educational attainment, and living arrangements. Also reported in the interview survey are the number of visits to physicians, medical specialists, episodes of hospitalization, and self assessment of health. Dental questions which used to be part of the HIS core were dropped in 1982 and a dental supplement was included in 1983 and will be repeated in 1986. In 1984, the NHIS included a special supplement on the elderly.

The National Health and Nutrition Examination Survey is one of the continuing NCHS programs designed to obtain the type of health information which can best, or only, be determined by direct physical examinations, tests, and measurements on the population. Assessments of general health and nutritional status are made on a national probability sample of persons 6 months through 74 years, and specifically, for population groups at high risk of poor nutrition, including the aged. The examination screens for such conditions as anemias, diabetes, kidney disease, heart disease, liver disease, gall bladder disease, hypertension, allergies, osteoarthritis and disc degeneration in the cervical and lumbar areas of the spine to determine the total prevalence of these major chronic health conditions, whether known or previously unknown or undiagnosed. In addition, information is obtained on the extent of limitation of activity from them and the medical care sought.

Evaluation of nutritional status are made from dietary intake and food frequency data interrelated with physical examination, medical history and biochemical data. These data are usually shown by age and other relevant demographic and socioeconomic characteristics such as family income, education, race or ethnic background. Since the sample size in this survey has not been adequate to allow detailed estimates regarding the health of Mexican-Americans, Cuban-Americans and Puerto Ricans, the Hispanic Health and Nutrition Examination Survey recently has been conducted to provide information comparable to the above for this rapidly growing minority group.

The National Nursing Home Survey (NNHS), inaugurated in 1973, is a continuing series of national sample surveys of nursing homes, their expenses, residents, and staff. The basic age groups presented in the publications are: under 65, 65-74, 75-84 and 85 and over, although some data are presented in 5-year intervals between the ages 65-95. Residents data include sociodemographic characteristics; health, functional and mental status; diagnosis; services received; charges; and sources of payment. Data on facility and staff characteristics, as well as on cost of providing care are also collected.

The initial NNHS was conducted from August 1973 to April 1974 and the second was conducted from June to December 1977. The 1977 survey was broadened to collect data on discharged residents, discharge planning by the facility, communication of needs by residents, measures of social activity, amount of monthly charge paid by the primary source of payment, facility revenues, and flu shots received by residents. The third NNHS was conducted from August 1985 to January 1986. In addition to some basic information collected in earlier surveys, the 1985 survey has been expanded to include the collection of information from the relatives of recent nursing home patients.

The National Hospital Discharge Survey (NHDS) measures morbidity associated with hospitalization in short-stay non-Federal hospitals. Information is obtained from a national sample of medical records of patients including detailed diagnoses and surgical and non-surgical procedures. Utilization measures including discharge rates and average lengths of stay are reported annually by diagnostic categories, by type of surgery, by characteristics of the patient and by characteristics of the hospital. Data are usually presented by broad age groups but data by any grouping are available on special request. The latest published data from the NHDS cover hospital utilization in 1984.

The National Ambulatory Medical Care Survey, another program of the Center, is designed to explore the provision and utilization of ambulatory medical care in the doctor's office. Data are provided on the number and rate of office visits by physician's specialty, type of practice, and geographic location and by the patients' age, sex and race. Also provided are the number of visits by patients' medical problems, and physicians' diagnoses, treatment, and disposition. One report on 1975 data described the visit experience of persons 65 years and older and how their experience differs from that of other age groups. Recently, a study of the age group 75 years and over was completed using 1980 and 1981 data. Other reports deal with visits to internists, gynecologists, and other specialties, visits by women, visits for various diagnoses, and biennial summary reports covering all major data items collected. The survey was done annually from 1973 through 1981. The most recent survey was conducted in 1985.

A working Group on Surveys of the Aging has been established within NCHS to coordinate the data collection and release activities associated with the 1985 NNHS, the 1984 NHIS Supplement and the 1986 National Mortality Survey.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

LONG TERM CARE

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The sample for the 1977 NNHS was drawn so that State estimates could be obtained for five States. An analysis of State variation in long-term care utilization and in the characteristics of the noninstitutionalized elderly indicates some striking differences. Many factors have influenced the development of long-term care systems in individual States and must be taken into account when evaluating these systems. A detailed discussion of this analysis can be found in Health, United States 1983.

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II. HEALTH RESOURCES AND SERVICES ADMINISTRATION

Bureau of Health Professions

AGING

Nursing Special project activities supporting aging in FY 1985 totaled $300,000. Projects included inservice educational programs for licensed practical nurses working with the aged, gerontological training programs for nurse educators, and educational programs for practicing nurses in the assessment and management of the frail elderly in an effort to increase the number of elderly who can be maintained in their homes. Additionally, an assessment instrument to identify self care behaviors practiced by the community based elderly is being developed.

In FY 1985 $1,537,490 was awarded to projects which emphasized aging/geriatrics. Registered nurses are prepared as geriatric/gerontologic nurse practitioners. As nurses with advanced academic preparation and clinical training, they are prepared as primary health care providers to manage the health problems of the elderly. They provide comprehensive nursing care which includes: promotion and maintenance of health; prevention of disease; assessment of health needs and long term nursing management of chronic health problems. Emphasis is placed on teaching and counseling the elderly to actively participate in their care and to maintain optimum health. The Advanced Nurse Training program awarded $1,108,000 in FY 1985 to support curricula preparing clinical specialists in gerontologic and geriatric nursing.

The Nursing Research Grant program awarded $[illegible] in FY 1985 for projects studying older women's performance of breast self-examination, sleep and breathing patterns in perimenopausal women, life factor profiles in individuals with Alzheimer's disease, effects of an exercise program on physical factors and morale of elderly subjects, and improving compliance in elderly patients with head and neck cancer. In addition, a new cooperative effort with the National Institute on Aging is supporting clinical trails of behavioral therapies for urinary incontinence in the elderly.

In FY 1985 twenty-two predoctoral grantees and [illegible] graduate programs in family medicine provided training in geriatrics. In Residency Training in Family Medicine program, 42 grantees received funds to provide curriculum content in geriatrics and gerontology to medical students totaling $[illegible]. Additionally, twenty-four Faculty Development Training programs indicated training to medical students in this area. University of Massachusetts received $[illegible] for their efforts. Six of the Establishment of Departments grantees indicated providing geriatric training.

Under the Area Health Education Center program in FY 1985, 16 of 19 awardees that indicated emphasis in geriatric activities received $[illegible]. These awards impacted an estimated [illegible] individuals. The largest award was made to the University of California - San Francisco, totaling $[illegible].

General Internal Medicine and General Pediatrics Residency programs that thirty-eight [illegible] in [illegible] activities in FY 1985. An estimated [illegible] residents [illegible] medicine training. Eight programs [illegible] awards in their activity. The [illegible] award was [illegible] University - Department of Medicine. [illegible] positions, three awardees in the General Internal Medicine [illegible] Faculty Development Grant program [illegible] approximately six [illegible] activities.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION

INDIAN HEALTH SERVICE

Aging

The percentage of the population who are older American Indians and Alaska Natives has continued to increase through the preventive, curative and rehabilitative efforts of the Indian Health Service (IHS) and tribal programs. The IHS continues to provide services to this population within the resources available in conjunction with other Federal, state, private and tribal agencies and groups.

Specific activities consist of physical examinations, screening and diagnosing conditions that specifically affect this age group. Nutritional counseling of individuals and staff responsible for the care of the elderly is also available. Community Health Nurse home visitation and health education activities play a major role in the Disease Prevention and Health Promotion efforts targeted for this population.

The IHS provides consultation and technical assistance to those tribal groups that have established facilities and services for the elderly. This includes home health care, extended care and skilled nursing home programs. This combined effort can be expected to increase the life expectancy of the aged and improve their quality of health.

ALCOHOL, DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION

National Institute on Alcohol Abuse and Alcoholism

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ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute of Mental Health

Aging

Extent of Problem

Between 1900 and 1977, the percentage of elderly in the total U.S. population rose from 4 to 11 percent. By the year 2010, there will be more than 30 million persons over 65 and more than 13 million over 75. Mental problems are common in this age group. The dementias including Alzheimer's disease represent a devastating problem in this population that can only become worse as the "graying of America" moves into high gear. Their prevalence rises from 3 percent for people at age 65 to over 20 percent for those 80 years of age and older. At present, almost 3 million people 65 and older, mostly women, suffer from a dementia. In addition, depression is a relatively frequent and often unrecognized problem among the elderly, contributing to the high suicide rate within this population.

Five percent of the Nation's aged live in institutions. Of these, about 12 percent are in mental hospitals, with the remainder in nursing and other types of homes for the aged and chronically ill. Elderly patients in State and county mental hospitals comprise 9.5 percent of their admissions and 27 percent of their resident patients. Those in nursing and personal care homes are frequently in need of mental health services; approximately 50 percent of these have some degree of mental impairment, with senile dementia the most frequently observed condition.

Need for Specialized Research on the Elderly

Yet, much of the existing information about brain function, behavior, and mental disorders may not apply to older adults for a number of reasons. First, the information is based on research on young and middle-aged adults. Second, a number of physiological changes in brain function accompany the aging process. And third, numerous psychosocial changes which impact on the elderly have occurred in this country over the past decade.

Recent research has focused attention on the significance of age as a primary variable. Several studies suggest that certain widely used tricyclic anti-depressants (e.g., amitriptyline) can induce marked memory and learning impairment in elderly subjects, although others (e.g., desipramine) are far less troublesome. The utility of using a different kind of antidepressant, monoamine oxidase inhibitors, in aged patients is being studied. Other research indicates that age-related changes in the performance of psychoactive drugs could lead to serious adverse reactions in the elderly if dosage and scheduling are not adjusted to compensate for these changes. Treatment of sleep disorders in the elderly is problematic because the most widely prescribed medication for sleep, flurazepam, remains in the body much longer in elderly than in young patients. This causes several major problems including incapacitating daytime drowsiness. Studies are underway to examine the problems associated with pharmacologic treatment of sleep disorders and alternative drug treatments to those that are currently standard. In addition, research shows that special care needs to be taken in interpreting many neuroendocrine test results in aged patients to determine whether abnormal measures are related to age or mental illness. Preliminary findings from a study of older persons with a major depressive disorder indicate that the elderly respond equally well to behavioral treatment, cognitive therapy and brief psychotherapy.

The patterns of mental illness among the elderly should become much clearer in years to come through the Epidemiologic Catchment Area program. Included in this study will be an oversampling of the elderly in several sites, focusing on those 65 and older. The study should reveal not only prevalence, but risk factors for [illegible] treatment, as well as the burden they place on families providing care [illegible] between the NIMH and National Center for Health Statistics [illegible] will become available [illegible] of mental disorders in the [illegible]

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- Prevention of pathology among elderly at risk for mental illness;

- Geriatric mental health academic awards for the support of teacher/investigators in psychiatry and psychiatric nursing, and

- Clinical research centers in psychopathology of the elderly.

Extramural activities include the stimulation and support of research in such diverse areas from differential diagnosis, through the application of advances in PET scan technology, to the role of the family in sustaining, community-dwelling patients with Alzheimer's disease; consultation with service planners and providers over the design and delivery of mental health services; collaboration with the pharmaceutical industry, other corporations, foundations, and private sector programs in the development and support of research and the dissemination of materials and information and collaboration with other Federal programs where strong, well-established technologies and specialized expertise already exist.

Intramural Research

The objectives for research in the Institute's Unit of Geriatric Psychiatry are to test existing hypotheses and create new hypotheses relating to the social, psychological, cognitive and affective changes that occur through the aging process. Further, its objective is to perform research that illuminates the differences between normal aging and pathology, synthesizing work from specific disciplines as well as interdisciplinary efforts.

Research Training

National Research Service Awards, including fellowships and institutional awards at the predoctoral or postdoctoral levels, provide support for the training of research scientists in the area of mental health and aging. Four new awards and one continuation project were funded through the Institute's Aging program.

Clinical/Services Training

In geriatric mental health the number of well-trained specialists is so small in relation to the size of the problem, that NIMH training support is focused on the development of a cadre of teacher/clinicians who will influence the training of professionals in the core mental health disciplines. This is necessary because most older persons have their mental health problems treated by professionals who are not specialists in geriatrics.

The Institute's program in mental health manpower development and training has focused on training efforts designed to improve mental health and related services to the aging within both the established mental health service delivery system (e.g., State mental health hospitals, community mental health centers, etc.) and the mental health-related support systems (e.g., senior centers, long-term care facilities, etc.). In FY 1985, NIMH awarded 10 new

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The quite modest magnitude of clinical effects obtained with cholinergic drugs to date suggests to some investigators that either inadequate levels of the drugs are reaching the brain or that more complex intervention strategies are necessary. The former consideration led to a highly publicized pilot study at Dartmouth Medical School, in which the muscarinic agonist bethanecol was delivered through an implantable pump and catheter directly into the brains of four AD patients. This small study established that the procedure is workable and led to a grant application (MH40301, Robert Harbaugh, M.D., Dartmouth University, "Muscarinic Agonist Treatment for Alzheimer's Disease") that was approved and funded in FY 1985. This study will test the efficacy of the treatment in a larger, carefully controlled study and will provide a valuable test of the "cholinergic hypothesis." The possibility that more complex intervention strategies are necessary is strengthened by recent studies showing multiple neurotransmitter and metabolic deficits in AD. Among the combination treatment approaches now being tested clinically are two studies in which lecithin is combined with the "metabolic enhancer" piracetam. Pilot studies suggest that this combination may be of some therapeutic utility. Carefully controlled double-blind studies (MH29590, Steven Ferris, Ph.D., New York University, "Psychopharmacology of Neurotransmitter Systems in Aging"; MH32724, Suzanne H. Corkin, Ph.D., Mass. Institute of Technology, "Lecithin Precursor Treatment in Alzheimer's Disease") are now being supported to test this possibility. Both of these studies will be completed in the coming year.

Aside from both the straightforward and complex cholinergic interventions, a number of other treatments are being evaluated. For example, based on a pilot study suggesting that the opiate antagonist naloxone may be effective in treating Alzheimer's disease, a well controlled study of naloxone is now underway (MH38275, Barry Reisberg, M.D., New York Univ., "Opioid Antagonist Treatment of Alzheimer's Disease"). This study will be completed in the coming year, and the results will be of quite practical and theoretical interest. Among other diverse approaches to treatment is the possibility that certain brain peptides or their analogs may be effective in treating memory impairment. This possibility has recently been tested by several investigators (e.g., MH36609, Jared Tinklenberg, M.D., VA-Palo Alto, "Neuropeptides, Mood, and Memory in the Elderly") and the results have been generally disappointing. However, there are substantial problems in delivering these drugs to the brain, and trials with the technology introduced by Harbaugh and his colleagues may produce entirely different results.

On the very frontier of technology, two other studies (MH18215, Steven Ferris, NYU, "Mental Health in Aging: Drug Effects on Brain") are using Positron Emission Tomography (PET) to determine the nature of brain metabolic changes in AD and examine how these changes might be altered by various experimental drugs. Similarly, pioneering studies by Peter Davies and colleagues (MH38623, Peter Davies, Ph.D., Albert Einstein College of Medicine, "Aging and Dementia - Cholinergic Neuron Biochemistry") are examining the specific neurochemical deficits that occur in AD and pointing to new strategies for drug development.

In addition to pharmacologic intervention studies in AD, studies are underway to examine optimal behavioral management strategies. For example, an important study by Jerome Yesavage and colleagues (MH35182, Jerome Yesavage, Ph.D., Stanford University, "Memory and Mental Health in Aging") is examining the effects of memory training in patients with early AD.

Research aimed at solving two of the major impediments to clinical drug evaluation in AD is also proceeding at an extremely fast pace. The first of these impediments concerns the lack of concordance between drug effects observed in animal models of aging and AD and those observed in clinical trials. This problem is being addressed through a major collaborative effort involving NIMH staff, Drs. Steven Ferris and Charles Flicker at New York University, and Dr. Raymond Bartus at the American Cyanamid Company. The objective of this collaboration is the development of homologous behavioral tests in humans and non-human primates to allow effective screening of large numbers of drugs of possible utility in AD. A new animal model of AD is being developed and several homologous tests for humans have already been published. A second impediment is the lack of valid and reliable clinical assessment instruments for assessing drug effects in AD. This problem is being addressed through multiple collaborative research projects involving NIMH staff and through funding of innovative grants to develop new instruments. For example, collaborative projects are underway at New York University to develop psychometric tests closely related to AD symptomatology and at Massachusetts Institute of Technology to develop a standard test of apraxia, a frequent symptom of AD. Grants for test development relevant to treatment assessment in AD include MH38659, Elizabeth Clark, Ph.D., UCLA, "Tests of Logic and Inference in Alzheimer-Type Dementia", MH 39135, Robert Hart, Ph.D., Medical College of Virginia, "Rate of Forgetting in Dementia and Depression." Grant applications to develop a new and conceptually innovative assessment battery for treatment studies in AD have been submitted and are under review.

While memory impairments are usually considered the cardinal features of Alzheimer's disease, families of Alzheimer victims often complain most vociferously about the agitation, wandering, sleeplessness, and other psychiatric symptoms that can accompany the illness. Acute and chronic signs of depression are also often present in Alzheimer patients, but the symptoms are difficult to elicit, and the patients do not always conform to the customary profile of depression in the adult population. Thus, potentially reversible manifestations of Alzheimer's disease are frequently underdiagnosed. As part of the comprehensive treatment program on Alzheimer's disease, NIMH intramural researchers are currently studying the behavioral phenomenology associated with dementia and developing a series of new research instruments to better characterize and measure these psychiatric symptoms.

Earlier studies from the intramural Alzheimer program have shown that there may be biological links between geriatric depression and Alzheimer's disease in addition to the behavioral comparisons just described. Similarities in response to neuroendocrine challenges such as the dexamethasone suppression and thyrotropin stimulation tests as well as parallel reductions in cerebrospinal somatostatin in the depressed and dementia populations have led us to speculate about the possible response of Alzheimer patients to antidepressant medications. Preliminary findings from a pilot study of monoamine oxidase inhibitors have revealed encouraging behavioral results, so a long-term study of these agents in Alzheimer's disease has been initiated. While the connection between depression and dementia should not be exaggerated, the possible uncovering of any reversible or treatable aspect of Alzheimer's disease must be pursued aggressively as the other current therapeutic options are still quite bleak.

From a more theoretical point of view, the NIMH intramural Alzheimer program is continuing to assess the functional status of brain neurotransmitter systems in dementia by means of a series of pharmacologic challenge tests. In the last year, evidence has developed that may help in the earlier diagnosis of Alzheimer's disease by showing that dementia patients appear more sensitive to anticholinergic drugs than age-matched subjects without dementia. In addition, an extensive study of naloxone in Alzheimer's disease has been completed. Although demonstrating a lack of beneficial cognitive effects, this study did show behavioral changes and should provide a useful guide to other researchers investigating naloxone in dementia. Current projects are focusing on the response of Alzheimer patients to other neuropharmacologic agents such as specific cholinergic and serotinergic drugs. It is hoped that these and other ongoing tests will help in the development of new strategies for the characterization and treatment of Alzheimer's disease.

The majority of AD victims reside in a home setting with care provided by an informal caregiver, usually a family member. Continued family caregiving is a major factor in preventing institutionalization and providing needed services and support to the AD victim. Family caregivers, however, experience a variety of psychological, physical, financial, and societal burdens and stress which frequently place the caregivers at risk for developing or aggravating their own health and mental health problems. With prolonged caregiving activities, family units frequently become more vulnerable to dysfunction.

A specialized request for research grant applications in this area was issued in Fiscal Year 1985. The research grant announcement seeks applications which will increase knowledge and improve research methodology on family stress related to the care of individuals with AD and the development of family care and service delivery models. These applications focus on the generation of systematic information on: the nature, consequences, and interplay of stress associated with caregiving; factors associated with understanding and enhancing family support; the identification, treatment, and management of excess disability in AD patients and strategies to maximize their functional level at all stages of the disease; the prevention of psychopathology and the promotion of mental health among family caregivers, and research on the design and delivery of services providing treatment and clinical interventions for individuals with AD and for the family members who care for them. A separate report on this initiative is being prepared in response to a specific directive from the House Appropriations Committee.

In April of 1983, the Secretary of Health and Human Services established a task force on Alzheimer's disease, chaired by the Assistant Secretary for Health. The task force includes representatives from NIMH, three institutes from the National Institutes of Health, the Commissioner on Aging, and representatives of the Veterans Administration and Health Care Financing Administration. An NIMH researcher serves as the Executive Secretary. The task force coordinates research on Alzheimer's disease, shares information, identifies promising research directions, and provides a vehicle for translating the research into policy and program. The report of the task force has been completed. It provides a review of the most promising areas of research on Alzheimer's disease, and offers recommendations for future research directions.

Treatment of Psychosis, Depression, and Sleep Disorders in the Elderly:

Studies recently completed (MH34042, Douglas M. McNair, Ph.D., Boston University, "Tricyclic Antidepressants and Cognitive Toxicity") suggest that certain widely used tricyclic antidepressants (e.g., amitriptyline) can induce marked memory and learning impairments in elderly subjects, although others (e.g., desipramine) are far less troublesome. A study completed this year examined the utility of using a different type of antidepressant, monamine oxidase inhibitors (MAOIs), in aged patients (MH35176, Anastase Georgatis, M.D., New York University, "MAOI vs. TCA in the treatment of Geriatric Depression"). This study suggests that the MAOIs have a place in the treatment of depressed elderly patients, but that long-term treatment is associated with a number of quite problematic side effects. These issues are being explored in a follow-up study.

Sleep disorders are extremely common in the elderly and treatment is frequently problematic. For example, the most widely prescribed medication for sleep, flurazepam, remains in the body much longer in elderly than in young patients and may cause several major problems including incapacitating daytime drowsiness. Studies are now underway to examine the problems associated with pharmacologic treatment of sleep disorders and alternative drug treatments to those that are currently standard (MH34720, Joseph J. Tecce, Ph.D., Boston State Hospital, "Neuropsychopharmacological Studies of Sleep and Aging"; MH33688, Patricia N. Prinz, Ph.D., University of Washington, "Sleep/Waking Patterns in Dementia"; MH08975, Karl Rickels, M.D., University Hospital, Philadelphia, "Early Drug Evaluation in Neurotic Outpatients"). These studies have extremely important implications for the treatment of sleep disorders in the elderly.

In treating psychotic disorders in elderly persons, the major problem is the possibility of inducing the serious neurologic side effects that constitute tardive dyskinesia. A major study is now underway (MH30854, Jerome Yesavage, M.D., Stanford University, "Age, Neuroleptic Levels and Tardive Dyskinesia") to determine whether this problem can be controlled by carefully monitoring drug plasma levels and lowering dosage accordingly. This study will be completed this year and will have an immediate effect on the pattern of use of neuraleptic drugs in elderly patients.

Clinical Research Centers on Psychopathology of the Elderly (CRC/PE):

The CRC/PE Program is intended to provide stable, sustained support to a limited number of centers, each comprised of a core group of investigators who have access to elderly clinical populations, for the development of integrated sets of innovative, multidisciplinary, and in-depth clinical research studies of the mental disorders in later life. It is anticipated that such centers will provide a milieu which encourages creative thinking about promising hypotheses; a resource for the development of new clinical researchers, and an environment of excellence which will assure the highest quality research and leadership in their chosen areas of investigation. Centers are expected to have a specific theme or problem focus. A CRC/PE will be situated in clinical treatment settings with demonstrable interest in the study of mental health and aging. Centers are expected to have a treatment milieu in which behavioral and biological scientists and clinicians can interact and study problems of etiology, classification, assessment, mechanisms, course, and psychotherapeutic and/or somatic treatment of particular mental disorders common in later life. A specific announcement is available for this program.

In FY 1984, the first three awards in this program were made: centers at Stanford University and at the University of Washington will focus on issues of diagnosis, clinical course, and excess disability in Alzheimer's disease, while the new center at Duke University will focus on several aspects of depression. In FY 1985, two additional awards were made: the center at Philadelphia Geriatric Center will focus on assessment and treatment of depression in long-term care facilities and the center at UCLA will focus on the diagnosis of depression and issues of combined dementia/depression.

at the University of Iowa, Iowa City. Memory tests conducted on a large, rural elderly population confirmed the relationship between memory and hypertension that, until now, has been observed only in much smaller studies of younger adults. Subjects were read a list of 24 words and immediately asked to recall as many as possible. Significantly lower memory scores were found among both men and women with diastolic hypertension (where the diastolic and usually systolic pressures are elevated), but not those with ISH. No relationship was found between the memory test scores and the use of antihypertensive medication or amount of physical activity.

Dr. Wallace cautions that these findings do not necessarily imply a causal connection. Rather, some underlying process, either genetic or environmental, may be responsible for the development of these concurrent problems. Furthermore, the prevalence of both hypertension and cognitive decline tends to increase with age. This compounds the problems associated with either condition.

These results point to the need for additional information about this relationship and demonstrate that large-scale studies using simple memory tests are feasible.

Behavioral Therapy Reduces Urinary Incontinence

Urinary incontinence is a common disorder that affects not only many institutionalized patients, but also many community-dwelling men and women. Estimates indicate that about half of all nursing home residents and 7 to 14 percent of noninstitutionalized adults are incontinent of urine.

Intramural scientists at the NIA's Gerontology Research Center (GRC) in Baltimore, Maryland, have been investigating the therapeutic effect on bladder control of a combination of physical therapies and behavioral training procedures in elderly patients affected by either stress incontinence, bladder hyperreflexia, and urge incontinence.

Of these three common types of urinary incontinence, stress incontinence is the most prevalent form, affecting almost half of all women at some time during their lives. It is characterized by the involuntary loss of small amounts of urine produced by such events as coughing, sneezing, or lifting an object. Patients with hyperreflexive bladders and urge incontinence often experience a problem when their bladders contract prematurely or suddenly and in an uncontrollable manner. By the time they realize this event has occurred, it is often too late to avoid wetting. This condition may occur as the result of a stroke or other cerebrovascular event, some other disease such as diabetes, or removal or resection of the prostate gland. Usually the cause is unknown.

GRC investigators worked with 39 elderly patients on an outpatient basis. Nineteen were identified as having stress incontinence; the remaining 20 had either bladder hyperreflexia or urge incontinence. Those patients with stress incontinence were initially placed on a habit-training program, which involved regular voiding at 2-hour intervals. Patients also underwent one to eight sessions of biofeedback therapy. This involved visual feedback of bladder and sphincter pressures critical to the patients' learning; exercises to strengthen their pelvic floor muscles. This training helped them to avoid incontinence during periods of physical stress.

The 12 subjects with bladder hyperreflexia and the eight with urge incontinence also began with behavioral interventions. However, emphasis was placed on learning how to cope with the urge to void. Patients needed to learn how to voluntarily inhibit their bladders during the contraction stage to prevent bladder contractions and to use their sphincter and pelvic floor muscles to avoid leakage.

The patients with stress incontinence required an average of 3.5 training sessions to achieve their degree of urinary control. Overall they reduced their frequency of incontinent episodes by an average of 82 percent.

Patients with bladder dysfunction (urge incontinence) also improved significantly. They showed an 85 percent overall improvement, and several became fully continent. The urge incontinent subjects had more variation, and some had a 100 percent decline in reported accidents.

Overall, about one-third of the patients seen by the GRC investigators achieved total continence following therapy. Typically afterwards, most patients experienced only one or fewer accidents per week over a four-week period.

These behavioral studies suggest that behavior therapy is an effective method for treating three major types of urinary incontinence in healthy, cognitively intact older men and women. This procedure has the potential for significantly reducing the medical and social problems linked to this frustrating condition. Building on these studies, five clinical trials of behavioral therapies in both institutionalized and community populations are under way in cooperation with the Division of Nursing, Health Resources and Services Administration. GRC investigators, in addition, in concert with the Health Care Financing Administration, are extending their intervention studies to incontinent residents of a nursing home and chronic hospital facility at the Francis Scott Key Medical Center of the Johns Hopkins University in Baltimore.

Understanding and Preventing Causes of Hip Fractures Become Major Research Priorities

Hip fractures are a major cause of disability and death for older people. People over 65 account for 84 percent of the more than 200,000 hip fractures that occur each year in the United States. If no treatment or prevention strategies are made, the number of hip fractures will increase sharply to more than 500,000 per year by the year 2040. Personal and societal consequences of hip fracture include increased nursing home and hospital admissions, dependency on rehabilitation services and devices, restriction of daily activities, and emotional suffering.

Approximately 15 percent of all hip fracture victims die of complications attributable to the fracture or its treatment within 6 months; 50 percent of the surviving victims cannot walk. In the United States, the annual costs associated with hip fractures were estimated in 1984 to be over $6 billion.

Hip fractures are directly related to loss of bone strength caused by osteoporosis. Because hip fractures in older persons generally occur only after a fall, an increased risk of falling is an additional cause of fractures.

For some time scientists have recognized the importance of research in osteoporosis; research projects continue to yield useful information about the causes, treatments, and prevention of this disorder. More recently, attention has been directed at the problem of falls and gait disorders as they relate to fractures. It is increasingly clear that osteoporosis alone is not the sole or even primary cause of most hip fractures. Victims must experience a trauma, usually a fall, in order to break a bone. For several years, the NIA has stepped up efforts to encourage and support research in the complex area of falls and gait disorders.

Osteoporosis. Osteoporosis is a degenerative bone disease affecting as many as 20 million Americans, most of whom are over 45 years of age. The disease results in brittle, fragile bones, especially among thin, white women.

NIA grantee Dr. B. Lawrence Riggs and associates at the Mayo Clinic in Rochester, Minnesota suggest that at least two, and possibly more, types of osteoporosis exist. Type I or "postmenopausal" osteoporosis is associated with estrogen deficiency in women who begin to show symptoms 10 to 15 years after menopause. Low, oral doses of estrogen are effective for slowing the rate of bone loss in women at-risk, and may prevent osteoporosis-related hip and wrist fractures. Estrogen replacement therapy has been shown to slow bone loss when begun as late as 6 years after menopause. Dr. Riggs and colleagues are evaluating the effects of treating patients with estrogen combined with progesterone (another hormone), which may reduce the related risk of endometrial cancer.

The body's decreasing ability to absorb calcium may contribute to Type II osteoporosis. This type occurs primarily in men and women over the age of 75 and results in more gradual bone loss than Type I. The effectiveness of calcitonin, a hormone that affects calcium metabolism, is being studied by Dr. Charles Chesnut III at the University of Washington General Clinical Research Center (GCRC) in Seattle. This work is supported by the NIA and the Division of Research Resources.

Calcitonin appears to increase indirectly the amount of calcium absorbed from the diet and incorporated into bone. The hormone is one of several that control the natural formation of new bone and the breakdown of old. Dr. Chesnut believes that regular doses of calcitonin given to postmenopausal women might lower their chance of developing osteoporosis. The hormone also seems to prevent postmenopausal osteoporosis from worsening. On the basis of the University of Washington GCRC study and another study conducted at Brookhaven National Laboratory on Long Island, New York, the Food and Drug Administration recently approved calcitonin for treatment of patients with osteoporosis.

Vitamin K is another nutrient in addition to calcium and vitamin D that may be implicated in osteoporosis. Vitamin K is essential for the synthesis of osteocalcin, a protein with calcium-binding properties needed for the mineralization of bone. Under the direction of NIA grantee Dr. Paul M. Gallop at the Harvard University and Children's Hospital Medical Center in Boston, researchers have discovered that Gla (gamma-carboxyglutamic acid), a component of osteocalcin, is excreted in the urine and may be a reliable indicator of vitamin K deficiency and the status of bone metabolism. The investigators hope to perfect a noninvasive method of detecting osteoporosis by measuring serum osteocalcin and urinary Gla.

The value of exercise for preventing bone loss in men has been demonstrated by a team of experts in Honolulu, Hawaii. NIA-supported researchers led by Dr. Richard Wasnick at Kuakini Medical Center found that strenuous exercises—such as jogging and racquetball—performed at least once a week were related to higher bone mineral content. They are also studying the effectiveness of estrogen combined with thiazide, a diuretic used for the treatment of hypertension. This drug also decreases the loss of calcium in the urine. Women who have received this combination treatment and men who have taken thiazide on a long-term basis for hypertension show beneficial effects on bone mineralization. Studies are continuing on the potential therapeutic value of this drug.

Other positive results on the value of exercise were observed by NIA grantee Dr. Everett L. Smith and associates at the University of Wisconsin in Madison after a 3-year regimen of stretching, aerobics, and upper-body conditioning in women experiencing menopause. The Wisconsin team has observed seasonal changes in bone mass which may reaffirm the usefulness of sunlight in preventing weak bones. To what extent these changes in bone mass are attributable to variations in physical activity and diet brought about by the change of seasons is unknown.

The NIH Consensus Development Conference on Osteoporosis, which was held in April 1984, concluded that the National Research Council's current Recommended Dietary Allowance (RDA) for calcium of 800 mg daily is too low, particularly for postmenopausal women and possibly for elderly men as well. The Consensus Panel recommended that an increase in calcium intake to 1,000 to 1,500 milligrams a day beginning well before the menopause will reduce the incidence of osteoporosis in postmenopausal women. In addition, the Panel noted that normal levels of vitamin D are required for optimal calcium absorption. Persons who do not receive adequate daily sunlight exposure, such as those confined to home or to a nursing facility, are at special risk for vitamin D deficiency. The current RDA for vitamin D is 400 international units daily.

Falls and Gait Disorders. Gait, balance, and posture are complex functions that are often altered by disease and aging processes. The relationship between gait disorders and falling episodes is unclear, and attempts by investigators to correlate various dysfunctions in the central nervous system with frequency of falls have not produced precise conclusions.

For some time, it has been recognized that many older people, especially the infirm and the homebound, lose lower extremity strength and experience a decline in gait speed and step size. Despite this recognition, the relationship of ankle-flexing ability and ankle and knee strength to risk of falling has not been thoroughly examined in older individuals. Dr. Leslie Wolfson and colleagues at the Albert Einstein College of Medicine, Yeshiva University, New York, participating in a Teaching Nursing Home project sponsored by the NIA, have conducted such studies.

They checked muscle strength and flexing ability of the knees and ankles in two groups of nursing home residents. The 17 patients in the study group ("fallers") had a history of one or more unexplained falls in the prior year; they were compared to 17 similar but non-falling control individuals. The participants were screened to eliminate those who had defined reasons for falling, such as previously diagnosed neurologic disease, severe arthritis, or severe vision problems.

Four muscle groups in the knees and ankles were examined by the researchers. Compared to the non-fallers, the fallers were found to have a significant decrease in strength of the knees and ankles. Ankle-flexing ability in fallers was markedly diminished compared to non-fallers. Ankle neuromuscular dysfunction in the elderly faller may account for postural instability in general; extreme loss of flexing ability may be particularly responsible for backwards falls.

These findings add to the small but increasing body of knowledge about the effects of specific physiological changes associated with older age and the risk of falling. The recognition of possible deficits in the neuromuscular components that control balance and gait could lead to the development of methods to strengthen and retrain coordinated function in this critical area.

In November 1985 the NIA issued a Request for Grant Applications on the topic of neurologic, muscular, perceptual, and cardiovascular aspects of falls and gait disorders in elderly people. Investigations being solicited include those that will identify both the physical factors and the underlying pathological or physiological mechanisms responsible for the various types of falls and disabling gait disorders common in older people. This invitation to the research community to focus attention on this important topic reflects the Institute's viewpoint that falling and gait disorders are not an inevitable accompaniment of old age, but are the result of diseases and potentially treatable conditions. Results from such research will help investigators design future clinical trials of interventions to prevent falls and gait disorders.

In another effort, the NIA sponsored a workshop in 1984 on the biologic and behavioral aspects of falls in the elderly. The proceedings of this workshop focused on the causes of falls and their contribution to injuries in older people. Although prevention strategies were not the main focus of the workshop, a better understanding of the causal factors involved in falls can lead to better ways of preventing such accidents. This publication should help stimulate new research projects that will ultimately lead to a more thorough understanding of falls.

New Studies on the Very Old Provide Valuable Data

The number of persons over age 85 is growing more rapidly than any other segment of the American population. In 1980 2.3 million people were over age 85 and by the year 2000, 4.9 million will be; by 2040, when the baby boom cohort reaches its ninth decade, this group is expected to total 13 million.

Census data gathered from people over 85 years old have often been inaccurate in the past. This has been due in part to illiteracy, inhibitions about stating true age, and incorrect records of birth dates. Additionally, there have been no accurate studies of the health, education, income, and other general characteristics of this population.

NIA grantee Dr. Ira Rosenwaike, a demographer at the University of Pennsylvania in Philadelphia, has recently completed a series of studies in which he has reevaluated existing Census data on this diverse population.

Dr. Rosenwaike found that, although income of the extremely old is on the rise, it is unequally distributed. His data confirm two previous findings: that more very old women than men are dependent upon government programs and that women far outnumber men at the oldest ages. Although the number of chronically ill elderly in this age bracket is growing rapidly, there is a clear trend within the healthy segments of this population toward living independently for as long as possible. However, in geographic areas where there are large proportions of people over age 85, it is predictable that all aspects of life that involve health care provision and social services will be significantly affected.

As a result of these studies, Dr. Rosenwaike emphasizes that living longer does not necessarily mean living better. He is convinced that alternative community services will have to be developed for the great number of old people in our future communities. Population growth through decreased mortality may not attract as much attention as the baby boom, according to Dr. Rosenwaike, but the justification for studying the extremely old lies in socioeconomic reality. Researchers and planners in gerontology will need to institute the necessary provisions for the continued tremendous growth of people over 85 years old.

People Over 85 Show Gender Differences in Physical and Mental Health, But Not in Ability to Function

NIA grantee Dr. Marie Haug at Case Western Reserve University in Cleveland, Ohio, has examined longevity and gender differences in the elderly. She has found that women over age 85 experience greater physical and mental impairment than men the same age, while the ability to function in daily activities is similar in the two sexes (see Figure 1). Though these are early findings, the implication for the general population is that men tend to remain relatively healthy for a greater part of their lives whereas women tend to develop more chronic physical and mental diseases that result in longer periods of illness.

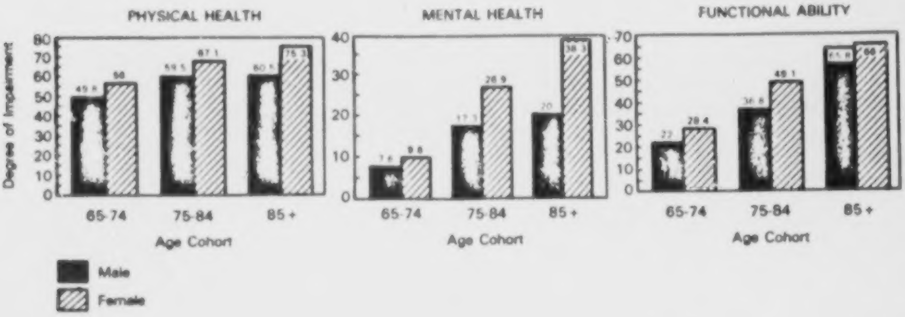

Figure 1

These are preliminary results from a 1984 follow-up* of survivors of the sample from the original 1975 Cleveland General Accounting Office study on the elderly; the characteristics of these individuals were found to be similar to those of elderly persons throughout the country. Dr. Haug's results point to the possibility that the use of health resources by older people in future years will vary depending on gender—women will be more likely than men to require formal medical care.

Use of Physician Services Found to Decrease Among the Very Old

A decline in the use of physician services among octogenarians was observed in a recent study of health care utilization among 50,000 community-residing older persons. Dr. Fredric Wolinsky at Texas A&M University in College Station analyzed cohorts of persons aged 56-59 and 84-87 over a period of 8 years. The first phase of the project confirmed the conventional wisdom that the use of health care services increases with age. An unexpected and unexplained phenomenon was noted, however: Among the oldest subjects, there was a slight decrease in the use of physician services. Because of the lack of data on the very old, it is unknown whether this decline in the use of physician services continues among those in their 90's and beyond.

Phase II of this study will involve further analyses to determine the relationship between race, sex, insurance coverage, and health status and the use of health care services among older persons. It is hoped that this phase of the project will shed light on the patterns of health care utilization, particularly among the oldest subjects.

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*The project was part of an NIA Teaching Nursing Home grant under the general direction of Dr. Amasa Ford.

Human Factors Engineering Offers Practical Approaches to Everyday Problems of Old People

Opening a refrigerator door may not seem that difficult a task, unless you suffer from arthritis or the seal that holds the door closed is stronger than you are.

Soon, computers and robots may be available to assist people who struggle to do the many things normally taken for granted. While 95 percent of all elderly persons live in their own homes, many require some kind of assistance in order to cope or merely to do the things they have always done. For several years, the late Dr. Martin Faletti received an NIA grant to examine some of the problems that healthy older people, and older people with physical disabilities, might encounter when doing daily household tasks and routines.

Dr. Faletti and his colleagues at the Miami Jewish Home and Hospital for the Aged in Miami, Florida, have looked at how Parkinson's disease and other neuromuscular disorders can make a chore of something as simple as getting in and out of a chair, how arthritis can affect an old person's ability to make a meal, and how technology might address these and other problems.

Of course, many older people live with family members who can accommodate such simple needs. Those who live alone can hire home aides to help with cooking and cleaning, but such care is often expensive, if available. Dr. Faletti's research is being applied toward a full range of efficient affordable devices that vary from a comfortable chair that assists the person trying to stand to a robotic arm that can pour a cup of coffee or open a screw-top jar. Technology is even envisioned which someday might make a full meal.

Dr. Faletti's colleagues hope to move beyond the kitchen to other rooms in the house and to look at other types of household chores. They also hope to create the software to convert what is now a computer-based robotic system into a voice-activated one, and at the same time, to build in an emergency call system. This type of human factors research is designed to help keep older people active, independent, and out of institutions.

Early Retirement is Influenced by Type of Occupation

New findings from a recent labor force analysis suggest that the type of work one has been engaged in may affect when one retires. Dr. Mark D. Hayward of the Battelle Memorial Institute in Seattle, Washington, reports that white collar workers and manual laborers are influenced by different factors when making early retirement decisions.

A survey of 15 million men revealed that those in "primary sector" jobs—which require high cognitive ability and social skill and afford greater choice and flexibility—are more likely to retire before age 62 than men in "secondary sector" jobs—which are more physically or environmentally demanding. However, when those in primary sector jobs decide to continue working, they remain in the labor force longer than those in secondary sector jobs.

Features of primary sector jobs that appear to increase the likelihood of early retirement are tenure, wages, compulsory retirement regulations, and employer-provided pension programs. Workers in these jobs report better health, better pension coverage, higher educational levels, and greater assets. No one attribute, however, stands out as the sole contributor to the likelihood of early retirement.

Manual laborers were less likely than their primary sector counterparts to give poor health as the reason for retirement. Dr. Hayward speculates that such workers, being less able to cope with the financial costs of health care after retirement, value the economic benefits of work. Secondary sector workers also may view leisure time as having negative connotations, and continue to work as a means of preserving self-esteem.

The study also finds that, among secondary sector employees, double pension coverage does not significantly increase the odds of retirement before age 62. This indicates that past research may have overestimated the pecuniary influence of pension benefits and challenges the notion that pensions may provide "avenues of escape" from unpleasant work environments. Age-eligibility criteria for pension benefits may play a role in early retirement decisions as well. Such findings could have important implications for formulating private pension policy and retirement incentives for older workers.

Psychosocial Risk Factors Are Important Determinants of Health in Older Persons

While it has long been intuitively known that lifestyle factors are important to one's health, scientific evidence is accumulating that show this to be true, not only for the middle-aged, but also for older people.

Research by NIA grantee Dr. George E. Kaplan, at the California Department of Health Services in Berkeley has demonstrated that behavioral characteristics as well as aspects of social and psychological life are significantly related to the risk of disease and physical disability. These results are based on the well-known Alameda County study. In this study, 7,000 residents between the ages of 16 and 94 were followed between 1965 and 1983. Subjects were interviewed at 9-year intervals on measures of physical and psychosocial well-being to assess age-related changes associated with risk factors for mortality, morbidity, and functional disability.

Smoking, physical inactivity, and being over- or underweight were found to be important behavioral risk factors for persons of all ages.

Those older persons who were socially isolated were found to be at a 20 percent higher risk for mortality than those who reported frequent contact with close friends and relatives. Similar results were seen for those living in poverty areas.

The investigators also measured functional impairment caused by a chronic condition acquired during the study (such as diabetes, stroke, or arthritis). Being unmarried and being depressed were the factors most frequently associated with risk of disability.

Dr. Kaplan asserts that the associations of psychosocial and behavioral risk factors are at least as strong as biological risk factors and serve as important determinants of health in old age. The study finds no evidence to support the statement that risk factors are unimportant for older people, as some have suggested. In fact, the results argue strongly against the notion that poor health and disability are the inevitable consequence of old age, and suggest the validity of preventive health interventions for all ages.

Case Examples Shown to be More Effective than Statistics in Conveying Health Information

Recent research points to the effectiveness of imagery as a means of conveying important health information to older persons. The use of vivid illustrations and case examples greatly increases the impact of health promotion messages. NIA grantee Dr. Karen S. Rook at the University of California at Irvine finds this strategy to be especially relevant in reaching elderly persons who may have difficulty remembering abstract information.

In a review of the content of 49 health promotion brochures, Dr. Rook found that less than 2 percent of the publications cited case histories; 12 percent had information on how to modify health practices; and 16 percent provided advice on how to cope, or answers to anticipated questions. On the other hand, more than 50 percent of the publications emphasized statistical information (abstract) on the magnitude of a health threat.

In further exploratory studies comparing the impact of case histories to abstract information, Dr. Rook has found vivid information to be a more persuasive method of communication among both younger and older women. Specifically, those women who were most apathetic about a potential health threat were most likely to be influenced by the vivid case history. The technique is also effective for younger persons who may perceive the information to be of little personal relevance but for whom early intervention is particularly important in preventing the consequences of degenerative diseases like osteoporosis.

The primary consideration in designing health education messages is to make the information as realistic and personally meaningful as possible. Dr. Rook also suggests that messages be realistic about what to expect—the good as well as the bad. She advises health educators to incorporate suggestions on how to cope with undesirable effects of the new behaviors.

Although the use of vivid messages enhances recall, its actual impact on health behaviors is still unclear. The results of these studies, however, provide guidelines for more effective communication of health research materials to target audiences.

National Cancer Institute

The National Cancer Institute (NCI) funds many areas of research concerned with cancer and aging. These include epidemiologic studies that help to assess the age-specific occurrences of some cancers; basic biological studies that seek to define the cancer process in individuals of all ages; and studies that address the particular problems of the older cancer patient—including prevention, detection, treatment, and support systems.

Many cancers occur more frequently with advanced age; the incidence of prostate cancer, for example, rises sharply for men after age 40. NCI is sponsoring long-term, controlled trials to determine the most effective methods of hormonal therapy for this form of cancer. One approach under active clinical investigation is the use of LHRH agonists—compounds that are structurally similar to LHRH. LHRH (luteinizing hormone-releasing hormone) is a hypothalamic hormone that controls sex hormones in men and women. When given in large doses on a long-term basis, agonists of LHRH suppress the production of the male hormone testosterone. Dr. Fernand Labrie of Laval University of Quebec, Canada, has developed a treatment for advanced prostate cancer that combines LHRH agonists with flutamide, a pure antiandrogen drug, in an attempt to suppress all male hormones, including the low levels of androgen produced by the adrenal glands.

The NCI's cooperative groups of cancer specialists throughout the United States are testing this new treatment for prostate cancer. In the past year, a major study began to compare treatment with LHRH agonists alone and in combination with a pure antiandrogen. About 600 patients are expected to participate in these trials.

Another major cancer affecting predominantly older age groups is lung cancer. This disease is expected to claim more than 125,000 lives in the United States in 1985. Under contract to NCI, Dr. Richard S. Schulof and coworkers at George Washington University Medical Center, Washington, D.C., reported that, among 42 postradiotherapy patients with certain types of lung cancer, administration of a synthetic thymic protein improved overall and disease-free survival, particularly in patients with non-bulky tumors. The protein, a synthetic form of thymosin, appeared to help reverse some of the radiation-induced suppression of the patients' immune systems, a common side effect of radiotherapy. Thymosin is believed to help immature immune cells grow and develop. The George Washington University scientists are now treating other types of lung cancer with this protein. NCI cooperative groups, comprised of participating physicians from many institutions, will be studying the use of thymosin in expanded, multicenter clinical trials.

Ways to improve the treatment outcomes and quality of life in cancer patients, particularly older ones, are always being sought by NCI. Institute grantees Dr. Barrie R. Cassileth and coworkers at the University of Pennsylvania Cancer Center, Philadelphia, reported that social and psychological factors played no discernible role in extending survival or time to relapse in 359 patients diagnosed with cancer. The scientists studied patients whose cancers were too far advanced for surgery and patients with early breast cancer or melanoma. This study did not address the possibility that psychosocial factors or events might influence either the cause of the disease or the outcome for patients with more favorable cancer diagnoses. The study does suggest that, for patients with advanced cancers and those at high risk of recurrence, the inherent biology of the disease alone determines prognosis, overriding the potential influence of psychosocial factors.

At the Center for the Study of Aging and Human Development at Duke University in Durham, North Carolina, NCI grantees recently reported the results of a large cooperative group study of the impact of age on the response to treatment, survival, and drug toxicity in patients with multiple myeloma, a malignant tumor of the bone marrow. Drs. Harvey J. Cohen and Alfred Bartolucci reported that older patients did not experience more toxicity from chemotherapy than younger patients. These results may encourage more aggressive—and successful—treatment for many older patients.

National Heart, Lung, and Blood Institute

Cardiovascular disease remains the chief cause of death in the United States. Individuals over 65 years of age suffer 75 percent of the deaths from ischemic heart disease, which is caused by narrowing of the coronary arteries and a decreased blood supply to the heart. Strokes take a heavy toll not only in deaths but also in disability. The principal cause of heart attacks and strokes is atherosclerosis, which alters the open pathway of the arteries and constricts blood flow. Atherosclerosis is generally thought of as a disease of aging because it develops slowly over years, but early manifestations of the disorder are apparent earlier in life.

Nonetheless, the effects are most often felt in those individuals who have lived long enough to develop the fatty streaks that are the beginning of atherosclerosis and then to undergo the intricate process by which various biological elements combine to develop stiff fibrous plaques. Plaque eventually narrows the opening in an artery and changes blood flow from a smooth process to a pressured and irregular one.

Dr. Russell Ross, a National Heart, Lung, and Blood (NHLBI)-funded investigator at the University of Washington in Seattle, has recently described this process of atherogenesis and offered some hopeful news that some atherosclerosis can be experimentally reversed in animals.

Dr. Ross has long theorized that atherosclerosis is a form of primitive wound repair. He has speculated that the lining of the arteries may be injured—develop breaks or lesions—by exposure to cholesterol to factors possibly released during cigarette smoking, or from high blood pressure, diabetes, various genetic disorders, or viruses.

Dr. Ross and his colleagues have fed pigtail monkeys high cholesterol diets to induce arterial injury. These breaks may have differing effects on the lining of the artery or on its function and these effects are seen after about 5 months of this diet.

Dr. Ross, as well as other scientists, have experimentally injured arteries with other substances, such as the amino acid homocysteine or antigen-antibody complexes.

When a break in the lining or endothelium of the artery occurs, substances normally screened out by this barrier reach the smooth muscle layer of the artery. Then blood platelets adhere to the newly exposed tissue and smooth muscle cells begin to proliferate, initiating a process that is thought to lead to the formation of the deadly plaques.

Techniques of cell biology and molecular biology and the fact that human arteries are available for study when they are removed in the process of femoral artery bypass surgery have allowed for recent progress in understanding atherogenesis. Dr. Ross and his colleagues recently have used monoclonal antibodies to tag various types of cells in the arteries so that under the electron microscope the origin of each type of cell involved in the development of the various substances that comprise plaque can be determined.

Animal studies have also contributed to these basic findings. In an effort to limit one crucial step in the development of atherosclerosis, antiplatelet agents, including aspirin, have been administered to animals with promising success to change the character of the blood platelets. And, at least in animals, when levels of blood cholesterol are reduced to normal, the factor responsible for the lesions disappears. Dr. Ross has suggested that if the original injury is brief and nonrecurrent, the condition may be reversed and even healed. If the injury continues and is chronic, such as would be due to hypercholesterolemia (an excess of cholesterol in the blood), the lesions or changes in the artery walls may progress and the process that creates the plaques that eventually block blood flow would have begun.

Such basic research may yield diagnostic techniques to identify high-risk individuals and specific interventions that will slow or reverse the development of this deadly disorder.

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) conducts and supports many projects related to aging processes and to diseases common in the elderly. Basic studies of metabolic processes through all developmental stages, including aging, are reflected in many of the Institute's programmatic areas. Diseases under NIADDK's purview that are of special importance to older persons include the major diseases osteoporosis, osteoarthritis (degenerative joint disease), and benign prostatic hyperplasia (BPH).

Osteoporosis is a major underlying cause of bone fractures in postmenopausal women and older persons in general. It is a condition in which bone mass decreases, causing bones to be more susceptible to fracture.

NIADDK grantees are participating in a long-term clinical trial on fluoride therapy for osteoporosis. In addition to strengthening the teeth, fluoride helps increase bone mass. The levels of fluoride required to increase bone mass are greater than the fluoride available in most water supplies.

These projects, one conducted by Dr. B. Lawrence Riggs, Mayo Foundation, Rochester, Minnesota, and the other by Dr. Michael Kleerekoper, Henry Ford Hospital in Detroit, Michigan, are progressing and demographic data are now being collected.

Risk factors among women with vertebral fractures have been identified as being more prevalent than in women without fractures. These risk factors include early menopause either natural or surgical, osteoporosis in a first-degree female relative, and thinness. White women were found to be at higher risk than are black women.

A separate report on arthritis, rheumatic diseases and related disorders provides more highlights of NIADDK's osteoporosis research.

National Institute of Neurological and Communicative Disorders and Stroke

The nervous system, including those structures that govern hearing, speech, smell, and taste, is particularly vulnerable to the physiologic effects of aging. Within the Federal Government, the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) is the focal point for research on disorders that affect the nervous system. These include ones that have a pronounced impact on the elderly population.

NINCDS research on two major neurological disorders affecting the elderly—stroke and Alzheimer disease—is described in separate reports.

Chemosensory loss. This year a comprehensive study of the much-overlooked sense of smell determined that this "chemosense" can deteriorate over time much like hearing does.

At the NINCDS-supported University of Pennsylvania Clinical Smell and Taste Research Center in Philadelphia, Dr. Richard Doty measured the olfactory function of nearly 2,000 people ranging in age from 5 to 99 years. His results show that the ability to identify specific odors begins to wane after age 50 and decreases sharply after age 70. Nearly 60 percent of individuals aged 65 to 80 showed a substantial loss of smell, and 25 percent had no sense of smell. In persons aged 80 and older, 80 percent had a severe loss, and at least half of these patients had lost their sense of smell entirely. The tests also revealed that women retained more smelling ability than men.

These findings help explain why older people are less likely to become aware of fires and gas leaks in the home in time to protect themselves, and why many elderly people eat poorly, complaining that their food lacks flavor.

The Aging Ear. Presbycusis, or hearing loss associated with aging, results primarily from cumulative damage to the ear's hair cells from various causes, including noise, disease, and drug toxicity. Two NINCDS-funded scientists are investigating the anatomy and function of the human hair cell to determine why this structure is so vulnerable to the effects of aging.

In his studies of hair cells over the past year, Dr. Albert J. Hudspeth of the University of California at San Francisco has found that the tip of the hair cell directs the flow of electric current which regulates the cell's response to sound. Dr. Dennis Drescher of Wayne State University in Detroit, Michigan, recently found evidence that an as-yet-unidentified neurotransmitter governs the hair cell's ability to relay sound messages to the brain.

By understanding more about normal hair cell function, scientists may be able to determine what goes wrong in presbycusis and find ways to treat and prevent this disease.

Hearing Aid Technology. A pioneering NINCDS grantee is using state-of-the-art electrical engineering techniques to develop an improved hearing aid. At the City University of New York, Dr. Harry Levitt this year began testing a new hearing aid designed by his research team. Like the black box in airplane cockpits, the hearing aid records continuously what is said. By pressing a button, the wearer can play back the last sounds recorded. The new hearing aid has been specially engineered to screen out background noise and block the unwanted effects of room reverberation which pose a special problem for hearing aid users in churches, concert halls, and other cavernous places.

Since many elderly patients become dissatisfied with their hearing aids and discard them, progress toward improved devices offers new hope for the elderly to continue active participation in daily life.

The Aging Brain. Certain brain structures appear to be especially hard-hit by the aging process, while others seem immune to aging's effects. This year, Drs. Henry Wagner and Dean Wong, NINCDS grantees at The Johns Hopkins University in Baltimore, Maryland, used positron emission tomography (PET)—a scanning technology that enables scientists to look at the structure and function of the living brain—to study brain chemistry in the elderly. They showed that activity of the brain chemical dopamine decreased over time in some parts of the brain involved with movement, while in other parts dopamine activity remained normal. These studies also produced evidence that dopamine activity loss proceeds faster in men than in women. Research has linked dopamine loss to Parkinson's disease, cerebral arteriosclerosis, and senile dementia in the elderly.

New evidence was reported this year of a possible connection between reduced dopamine activity and a vitamin B-6 deficiency. Drs. Wagner and Wong discovered that plasma levels of vitamin B-6 dropped as patients grew older. In addition, there was evidence that a vitamin B-6 deficiency alters dopamine metabolism in rats. Such information could conceivably be important in a future therapy to correct dopamine levels.

National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases (NIAID) conducts and supports research leading to better methods of preventing, diagnosing, and treating allergic, immunologic, and infectious diseases. The elderly are especially vulnerable to many of these conditions because the immune system becomes less efficient with aging.

Shingles, or herpes zoster, occurs mostly among older adults and causes a cluster of painful skin eruptions that often follow nerve pathways on the back and abdomen. The rash usually clears up in a few weeks, but in some people the residual pain is chronic and debilitating.

Scientists have long believed that shingles is a reactivation of varicella-zoster virus (VZV), which causes chickenpox in children. New evidence by NIAID grantees and intramural scientists now verifies this association. Dr. William Ruyechan and his colleagues at the Uniformed Services University of the Health Sciences in Bethesda, Maryland, collaborating with intramural scientist Dr. Stephen Straus, compared viral DNA isolated from a patient with chickenpox with viral DNA from the same patient with a later case of shingles. The two DNAs were identical and therefore the second infection was actually a reactivation of the same virus.

Understanding the molecular biology of VZV will help scientists find out if experimental vaccines against chickenpox can prevent herpes zoster. For example, Dr. Ruyechan and his colleagues have determined the composition of some of the basic units of the viral DNA and have identified unusual forms of the DNA that may affect establishment of latent infection eventually leading to shingles.

Research by these investigators may also lead to more effective treatments for herpes zoster. They isolated from cells infected by VZV seven specific proteins that affect replication of the viral DNA and control of infection. These proteins are all potential targets for antiviral drugs.

An experimental vaccine that prevents chickenpox in children will benefit future older Americans if it can also prevent herpes zoster. Since the vaccine is made from live attenuated viruses, scientists have been concerned that the virus might remain latent in vaccinees and reactivate in later life to cause zoster. NIAID contractor Dr. Anne Gershon and her colleagues at New York University Medical Center, New York City, tested the VZV vaccine in children with leukemia who are at high risk of developing severe, even lethal chickenpox as well as zoster.

Their preliminary findings from this contract suggest zoster occurs less frequently in vaccinees than in individuals who have had natural chickenpox infections and when it does occur it appears to be milder. Further studies will determine if the vaccine produces long-term protection and prevents and lessens the effects of zoster many years later. If the vaccine continues to prove safe and effective, it may one day be used routinely to immunize children against chickenpox. It is also possible that such a vaccine given to older adults may boost immunity to varicella and thereby prevent or reduce the severity of zoster.

Infections from certain types of bacteria (gram-negative) are a frequent cause of death and morbidity in debilitated elderly patients. These bacteria can enter the bloodstream after severe injury, after extensive surgery, or when the immune system is functioning less efficiently because of age or disease. Once in the bloodstream, a toxic substance called endotoxin in the bacterial cell wall can cause shock and death. While antibiotics can kill the bacteria, they do not neutralize the dangerous endotoxin; in fact, they may temporarily increase endotoxin levels in the blood as the bacterial cells are destroyed.

NIAID grantee Dr. Elizabeth Ziegler and her colleagues at the University of California, San Diego, have shown that a vaccine made from a killed mutant form of gram-negative bacteria called J5 causes humans to make antibodies against gram-negative bacterial infections. The investigators used antibodies from the blood serum of healthy volunteers immunized in this way to produce an experimental J5 antiserum. It was administered to patients in intensive care units because of abdominal surgery or trauma. The J5 antiserum did not lower the incidence of gram-negative infections in these patients but did markedly reduce the rate of shock and death from these infections.

Using hybridoma technology, the investigators fused the lymphocyte making J5 antibody with a long-lived cancer cell. The resulting hybrid cell can produce almost limitless quantities of J5 monoclonal antibodies that protect against fatal infections from a variety of gram-negative bacteria. If further evaluation and clinical trials confirm the potency of this type of antiserum, it can be used as an adjunct to standard therapy for endotoxic shock.

National Eye Institute

Each year individuals 65 years and older make over 9 million physician visits for eye care—nearly one-third of all appointments with eye care specialists nationwide—for the diagnosis or treatment of aging-related eye disorders. Older Americans are understandably concerned about these disorders and the threat they pose to their quality of life. Without proper care, common aging-related disorders like age-related macular degeneration, glaucoma, dry eye, and cataract can cause impaired ability to read, drive a car, or enjoy hobbies and other life-long interests.

The chances of maintaining good visual health well into old age are better today than ever before thanks to research advances. The National Eye Institute (NEI) supports research aimed at improving the diagnosis, treatment, and prevention of aging-related eye diseases, thus reducing their impact on individuals, families, and society.

Age-related macular degeneration (AMD) is the leading cause of severe visual loss among people age 60 and older. Research on the treatment of neovascular AMD, a form of the disease that poses the most serious threat to sight, is being conducted by the NEI-supported Macular Photocoagulation Study Group (MPS),* headed by Dr. Stuart Fine of the Wilmer Eye Institute in Baltimore, Maryland. Since 1982, when MPS investigators first reported that argon laser treatment for neovascular AMD is beneficial, it has become the standard treatment for this disease. Now, the investigators are evaluating a different laser device called the krypton laser in the treatment of some patients who cannot be helped by the more commonly used argon laser.

An NEI intramural research team is studying possible long-term protective measures that may someday be used to keep AMD from reaching the stage when laser treatment is necessary. Patients are asked to protect their eyes from bright light by using specially tinted eyeglasses. In addition, the investigators are evaluating antioxidant medications that may help to slow or prevent aging-related changes in the retina. Researchers hope that these simple measures may reduce the risk of visual loss from AMD.

Dry eye is another very common aging-related disease that is under intensive study by NEI-supported scientists. Although it is not generally a blinding condition, it does cause acute discomfort. Dry eye occurs when tear glands fail to produce adequate moisture to bathe the front of the eye. These aging-related changes in the tear glands are accompanied by changes in the cells that cover the eye's surface. As a result of this disease process, the eye feels "scratchy" or painful and becomes more vulnerable to injury and infection.

A new topical ointment for the treatment of dry eye has been developed by NEI-grantee Dr. Scheffer Tseng at the Massachusetts Eye and Ear Infirmary in Boston. Research suggests that this ointment may reverse changes in the eye's surface cells and alleviate painful symptoms in some patients. In addition to Dr. Tseng's work, other NEI-supported studies seek a better understanding of aging-related changes in tears and the surface of the eye and are expected to lead to further progress in the treatment of dry eye.

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* The research centers participating in this grant-supported project are located in Baltimore, Maryland; Chicago, Illinois; Cleveland, Ohio; Detroit, Michigan; Iowa City, Iowa; Madison and Milwaukee, Wisconsin; Miami, Florida; New Orleans, Louisiana; Oklahoma City, Oklahoma; Portland, Oregon; and St. Louis, Missouri.

Glaucoma—increased pressure within the eye—is another eye disease that affects middle-aged or older people and is a major cause of blindness. About 1.5 to 2 million Americans have the common form of glaucoma. The NEI is supporting a program of basic and clinical research to learn more about the mechanisms that cause glaucoma and to develop more effective means of early detection and treatment.

Because standard topical medications are not always effective in counteracting abnormally high pressure within the eye and preserving vision in glaucoma patients, NEI grantees are investigating other therapies. Under the leadership of study chairman, Dr. Hugh Beckman at the Kresge Eye Institute in Detroit, Michigan, glaucoma specialists at medical centers in Atlanta, Boston, Los Angeles, Milwaukee, New York City, Philadelphia, Columbus (Ohio), Chicago, and New Orleans are participating in an NEI-funded clinical trial to determine whether argon laser treatment may be an effective means of controlling intraocular pressure and preventing visual loss in newly diagnosed patients with the common form of glaucoma.

NEI-supported research on cataract furnishes an excellent example of the potential benefits from studies aimed at prevention of aging-related eye disease. At present, there are more than 700,000 cataract operations a year in this country and that figure may continue to rise each year unless adequate preventive measures are found.

Recently, laboratory studies have begun to yield results suggesting that cataract prevention may one day be possible. NEI scientists are making great progress in understanding how oxidation—a gradual chemical process that occurs in the lens of the eye and in all other tissues—contributes to the development of cataract. With the benefit of such chemical clues, and others that will emerge from continued research, scientists and pharmaceutical firms may eventually be able to design drugs that will prevent or slow the development of cataract.

Thus research supported by the NEI is contributing to the prevention as well as the treatment of aging-related eye diseases, and is bringing us closer to the day when good vision can be expected to last a lifetime.

Division of Research Resources

Research on aging is conducted at more than 32 General Clinical Research Centers (GCRC's) supported by the DRR. More than 80 percent of the extramural inpatient research care funded by NIH takes place in the 78 GCRC's located in major U.S. medical centers. In addition, extensive outpatient research is also carried out.

Research on aging is also funded under the Biomedical Research Support (BRS) Program, which supports more than 9,000 pilot and regular health-related research projects, including 133 focused on aging, at 557 institutions in the U.S. A study conducted by BRS grantees at the Veterans Administration Medical Center and the University of Utah in Salt Lake City revealed that regular aerobic exercise can improve the memory and mental dexterity of the elderly. Individuals in the study ranged in age from 55 to 70 years. They were not disabled by any clinical form of dementia, but showed signs of memory loss and other mental impairments that often accompany old age. Those who participated in a 4-month aerobic exercise program scored significantly higher in tests of mental and physical abilities than those in control groups who exercised moderately or not at all. The mean scores of the aerobic exercise group improved in five of seven tests for memory and mental dexterity. In contrast, the two control groups scored higher on only one test each.

Dr. Robert E. Dustman at the Veterans Administration Medical Center and Dr. Robert O. Ruhling of the University of Utah have found that some of the increased oxygen that is transported in the body after exercise reaches the brain. Oxygen is necessary for the synthesis of neurotransmitters, which are crucial for a variety of mental functions. This might explain how increased levels of oxygen in the brain as a result of exercise could enhance an elderly person's mental capacities. The improvements in the volunteers' mental functions after aerobic exercise, without any accompanying improvements in their hearing or sight, suggest that this type of exercise primarily affects the brain and not the peripheral nervous system.

Much of the research being conducted on the elderly focuses on identifying and developing an understanding of the physiological changes associated with aging. One such change is an impaired ability to maintain a constant body temperature when exposed to cold. This is linked to an increased risk of death among the elderly during periods of very low temperatures. Research supported by the BRS Program and conducted by Drs. James A. Wagner and Steven M. Horvath at the Institute of Environmental Stress of the University of California in Santa Barbara indicates that impaired ability to maintain a constant body temperature is due, in part, to a compromised capacity of the elderly person's blood vessels to constrict in response to cold. Blood vessel constriction protects an individual from cold damage by preventing the loss of internal body heat through the skin.

In the California study, minimally clothed persons between the ages of 20 and 72, were regularly exposed to four temperatures ranging from 50 to 82 degrees Fahrenheit. A variety of cardiovascular measurements were made on the individuals during exposure to each temperature. At 50 degrees Fahrenheit the older subjects had significantly higher forearm blood flow, indicating ineffective constriction of the blood vessels in their extremities. In addition, blood pressure of the elderly subjects tended to increase at a higher rate in response to cold temperatures. Although these increased blood pressures were not dangerously high, elevated blood pressure in response to cold in older people already afflicted with high blood pressure might cause damaging complications beyond those induced by a lowered body temperature alone.

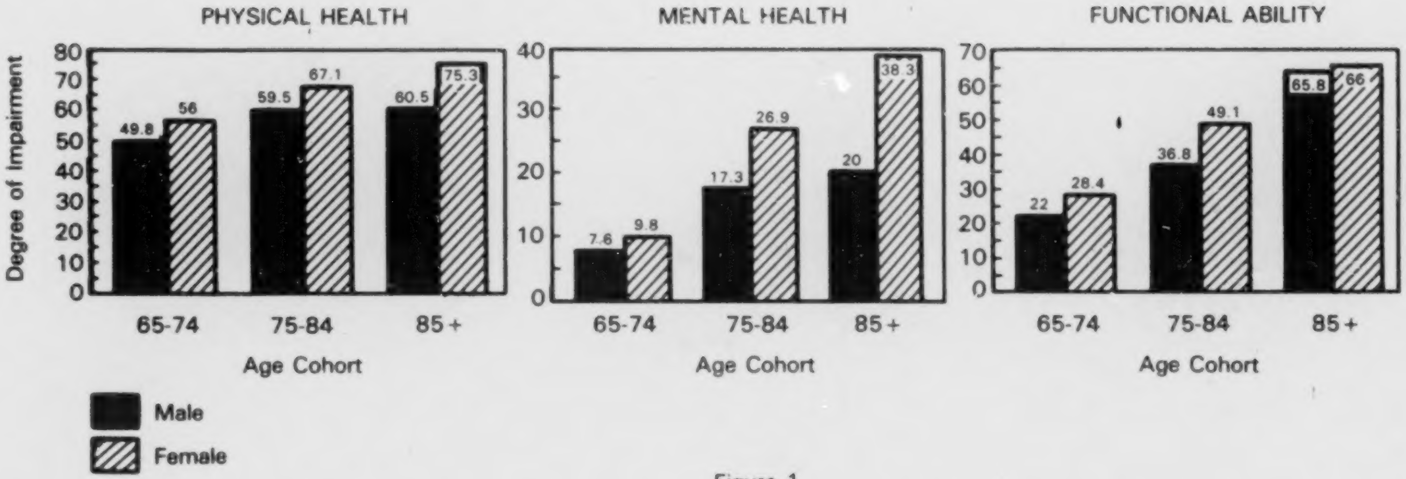

PHYSICAL HEALTH
MENTAL HEALTH
FUNCTIONAL ABILITY
Degree of Impairment
80
70
60
50
40
30
20
10
0
49.8
56
59.5
67.1
60.5
75.3
40
30
20
10
0
7.6
9.8
17.3
26.9
20
38.3
70
60
50
40
30
20
10
0
22
28.4
36.8
49.1
65.8
66
65-74
75-84
85+
Age Cohort
Male
Female

Figure 1

HEALTH CARE FINANCING ADMINISTRATION

A. Medicaid Program

Title XIX contains several provisions directed primarily to those persons aged 65: payment of Medicare premium, copayment, and deductible amount (for each assistance recipient); and coverage of inpatient hospital services in institutions for mental diseases. Long term care services, including skilled nursing facility services used primarily by the aged, as well as prescription drugs, eyeglasses, and hearing aids, are also covered by Medicaid.

The aged amount to a significant portion of Medicaid expenditures. About 37 percent of Medicaid program dollars will be spent on care for the aged in FY 1987, and it is estimated that 3 million people over age 65 (or about 14 percent of all recipients) will receive health care services. For most of these persons, Medicaid provides services which supplement and complement those provided by Medicare.

B. Medicare Program

Health Insurance Benefits

In FY 1987, an average of 32 million persons will receive Medicare protection. Of these, 29 million will be persons aged 65 or over, and 3 million will be under age 65, but disabled. Under Medicare, Hospital Insurance beneficiaries are protected against the costs of inpatient hospital services, post-hospital skilled nursing facility services and home health services. In addition, the voluntary Supplementary Medical Insurance program covers the cost of physician and related services. Both parts of the Medicare program provide for payment of these costs, subject to certain deductible and coinsurance amounts.

Under current law, payments to hospitals, extended care facilities and home health agencies for persons aged 65 and over under the Hospital Insurance program are expected to total an estimated $45.2 billion in FY 1987. Supplementary Medical Insurance payments for aged persons in fiscal year 1987 is estimated to amount to $23.3 billion.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Funds for Programs on Aging
(in Millions of dollars)

Health Care Financing Administration	1983	1984	1985	Initial 1986	1986 After Sequestering	1987
A. Medicaid	6,709	7,340	8,057	8,878	8,878	9,590
B. Medicare						
1. Hospital Insurance Benefits	33,707	36,733	42,432	43,219	43,015	45,179
2. Supplementary Medical Insurance Benefits	14,726	16,563	18,591	20,918	20,858	23,341

1/ Medicaid is exempt from Gramm-Rudman-Hollings reductions.

I. OASDI BENEFITS AND BENEFICIARIES

At the beginning of 1985, about 92 percent of all Americans age 65 and over were receiving Social Security benefits or were eligible to receive benefits if they or their spouses retired; about 94 percent of the people who reached 65 in 1984 were eligible for benefits. It is expected that 93 to 95 percent of the aged will be eligible for Social Security benefits by the end of the century.

At the end of September 1985, 36.9 million people were receiving monthly Social Security cash benefits (an increase from 36.3 million in September 1984). Of these beneficiaries, 22.3 million were retired workers, 3.5 million were dependents of retired workers, 33,477 were uninsured individuals receiving "special age-72" (Prouty) benefits, 3.9 million were disabled workers and their dependents, and 7.1 million were survivors of deceased workers.

The total monthly benefits paid to beneficiaries on the rolls for September 1985 was $15.3 billion compared to $14.4 billion for September 1984. Of this amount, $11.2 billion was paid to retired workers and their dependents, $1.4 billion was paid to disabled workers and their dependents, $2.7 billion was paid to survivors, and $4.5 million was paid to special age-72 beneficiaries.

Retired workers received an average benefit for September 1985 of $464 (up from $443 in September 1984), while disabled workers received an average benefit of $470 (up from $455). Retired workers newly awarded Social Security benefits for September 1985 averaged $470, while disabled workers received average initial benefits of $461. During fiscal year 1985 (October 1984 - September 1985), $184 billion in Social Security cash benefits were paid compared to $173 billion in fiscal year 1984. Of that total, retired workers and their dependents received $127 billion, disabled workers and their dependents received $19 billion, survivors received $38 billion, and special age-72 beneficiaries received $60 million. In addition, lump-sum death payments amounted to $207 million.

II. SUPPLEMENTAL SECURITY INCOME BENEFITS AND BENEFICIARIES

On January 1, 1985, SSI payment levels increased by $11.00 for an individual and $16.00 for a couple. Thus, beginning in January 1985, maximum monthly Federal SSI payment levels increased from $314.00 to $325.00 for an individual, and from $472.00 to $488.00 for an eligible couple.

During fiscal year 1985 nearly $10.6 billion in benefits (consisting of $8.7 billion in Federal funds and $1.9 billion in Federally-administered State supplements) were paid. Of 4.1 million beneficiaries on the rolls during September 1985, 1.5 million were aged, and 2.6 million were receiving SSI based on blindness or disability, although 514,000 of those in the latter category reached age 65 after they began receiving payments.

III. BLACK LUNG BENEFITS AND BENEFICIARIES

For September 1985, about 300,000 individuals received $85.0 million in black lung benefits which were administered by the Social Security Administration. These benefits are financed from general revenues. Of these individuals, 80,000 miners received $37.0 million, while 138,000 widows and 3,000 children not in the custody of a miner or entitled widow received $48.0 million.

Black lung benefits increased by 3.5 percent in January 1985 due to an automatic general benefit increase adjustment under the law. The monthly payment to a coal miner disabled by black lung disease is $328.20. The monthly benefit for a miner or widow with one dependent is $492.30 and with two dependents is $574.30. The maximum monthly benefit payable when there are three or more dependents is $656.40.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Funds for Programs to the Aged FY 1983 - FY 1987
(In Millions of Dollars)

	1983 Actual	1984 Actual	1985 Actual	1986 Estimate	1987 Estimate
IV. Social Security Administration					
Benefit Payments to Persons Age 65 and Over from Social Security Trust Funds......	$122,500	$129,300	$137,852	$146,235	$155,469
Payments to Persons Age 65 and Over From Federal General Revenue Funds:					
Supplemental Security Income Payments.........	3,593 1/	3,339 1/	3,649	3,719	3,806
Special Benefits for Disabled Coal Miners....	907	911	913	890	871
Subtotal, Payments to Persons Age 65 and Over From General Revenue Funds..................	4,446	4,250	4,562	4,609	4,677
Total, Social Security Administration..........	$126,946	$133,550	$142,414	$150,844	$160,146

1/ Due to Federal legislation mandating check payment on a banking day, the SSI program made 13 payments in FY 1983 and 11 payments in FY 1984.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SOCIAL SECURITY ADMINISTRATION

Mental Retardation

Purpose

The basic purpose of the social insurance programs (Old-Age, Survivors, and Disability) is to provide cash benefits to replace, in part, earnings that are lost to individuals and families when earnings stop or are reduced because the worker retires, dies, or becomes disabled. This program is contributory and self-supporting. Benefits are wage-related and entitlement to benefits is an earned right. In January 1974, the Supplemental Security Income program was added to those SSA administers. It provides payments to the needy aged, blind, and disabled, is noncontributory and is financed entirely out of general Federal revenues.

Historical Development

In 1935, when the original Social Security law was passed, the program was to have provided only retirement benefits to aged workers. In 1939, benefits for dependents and survivors were added and benefits become payable in 1940. Protection against long-term total disability--not only for disabled workers, but also for adult children (who became disabled before age 18) of disabled, retired, or deceased workers--was provided by the 1956 amendments. The 1967 amendments provided benefits for disabled widows and widowers age 50 and over. From 1939 through 1974, Congress granted ten general benefit increases in recognition of the fact that prices and wages had increased. In 1972, a section of P.L. 92-336 provided for an automatic benefit increase when the cost-of-living rises by 3 percent or more. Effective January 1974, payments under the Supplemental Security Income program began to qualified aged, blind, and disabled persons, including the mentally retarded.

Economic Impact

Old-Age, Survivors and Disability Insurance (Title II Programs)

Mental retardation is a major factor in about 70 percent of cases involving dependents or survivors who have been continually disabled since childhood. In fiscal year 1985 an estimated 405,000 mentally retarded adults, disabled in childhood, and retarded workers received $1.3 billion in benefits.

Standards as to the level of severity required in disability cases involving mental retardation are published in regulations. These regulations (published in 1985) have the effect of law and are available to the public and medical community.

The number of mentally retarded children under age 18 who receive Social Security insurance payments as dependents of retired, disabled, or deceased workers is unknown, since their benefits are payable regardless of disability. Under Social Security's "Childhood Disability" provisions, lifetime monthly payments can be made to a person age 18 or over who has been disabled by mental retardation--or other impairments--since childhood. In many cases, the monthly benefits enable the retarded childhood disability beneficiary to be cared for at home instead of in an institution. Furthermore, as more and more retarded people outlive their parents, the program offers reassurance to fathers and mothers who know that financial help for their disabled child will be provided even after their deaths. About 56 percent of the childhood disability beneficiaries are age 35 and over and about 33 percent of them are age 45 and over.

If the parents are dead, a relative or other party who has demonstrated a continuing interest in the beneficiary's welfare, a welfare agency, or a legal guardian may be chosen as representative payee to handle the benefit funds and to plan their use on behalf of the beneficiary. Each representative payee is held accountable for the way in which the benefits are used.

Supplemental Security Income (Title XVI)

An estimated 450,000 retarded individuals who are not entitled to benefits under the title II Disability Insurance program were receiving payment under the Supplemental Security Income program at the end of fiscal year 1985.

Activities and Achievements

Since 1970, the Social Security Administration has conducted biennial onsite reviews in State mental hospitals and schools for the retarded. The program focus is an indepth examination of the way in which these institutions are managing Social Security benefits on behalf of patients who receive their checks through an institutional official serving as "representative payee."

The observations and conclusions resulting from a State review are communicated to the State Commissioner for their use in the development of improved practices in the State's system. Findings also serve as a basis for SSA program and policy evaluation. The onsite approach is expected to strengthen relationships with the States, improve their understanding of their responsibility for optimum use of benefits when serving as representative payee, and open new channels for the discussion of problems and practices affecting the well-being of all beneficiary-patients in State mental institutions.

SSA has participated in the Special Program for Employment of the Handicapped since its inception in 1964 to employ the mentally retarded. It also has tried to generate interest in the program by private employers and other Federal agencies. In SSA, mentally retarded persons are successfully performing in such positions as mail and file clerks, messengers, operators of printing, xerox, card reader machines, and key punch machines. As experiment with the color coding of file cabinets and cartridges of microfilm has proven highly successful in broadening employment opportunities for the mentally retarded to an area of work which requires a very high degree of accuracy.

SOCIAL SECURITY ADMINISTRATION

Annual Payments to the Mentally Retarded
FY 1983 - FY 1987
(In Millions of Dollars)

	1983 Actual	1984 Actual	1985 Actual	1986 Estimate	1987 Estimate
Estimated Benefit Payments from OASDI Trust Funds..............	$1,175	$1,250	$1,300	$1,350	$1,400
Estimated General Fund Payments for Supplemental Security Income....................	1,045 1/	1,006 1/	1,183	1,282	1,391
Total, Social Security Administration....................	$2,220	$2,256	$2,483	$2,632	$2,791

1/ Due to Federal legislation mandating check payment on a banking day, the SSI program made 13 monthly payments in FY 1983 and 11 payments in FY 1984.

Alzheimer Disease

Obligations

Public Health Service:	1983	1984	1985	1986 Appropriation	1986 Available after Sequestering	1986 Revised 1/ Estimate	1987 Estimate
National Institutes of Health:							
National Institute on Aging	$11,848,000	$21,456,000	$28,830,000	$34,048,000	$32,691,000	$32,094,000	$32,094,000
National Institute of Neurological and Communicative Disorders and Stroke	8,678,000	11,700,000	12,826,000	14,030,000	13,427,000	13,117,000	13,117,000
National Institute of Allergy and Infectious Diseases	1,041,000	1,336,000	1,211,000	1,247,000	1,192,000	1,187,000	1,187,000
Division of Research Resources	604,000	709,000	1,034,000	1,055,000	1,010,000	1,010,000	874,000
TOTAL, NIH	22,171,000	35,201,000	43,901,000	50,380,000	48,320,000	47,408,000	47,272,000
Alcohol, Drug Abuse, and Mental Health Administration	--	8,450,000	8,600,000	8,750,000	8,374,000	5,886,000	5,886,000
TOTAL, PHS	22,171,000	43,651,000	52,501,000	59,130,000	56,694,000	53,294,000	53,158,000
Office of Human Development Services:							
Administration on Aging	--	163,800	1,127,600	900,000	861,300	600,000	600,000
TOTAL, DHHS	22,171,000	43,814,000	53,628,600	60,030,000	57,555,300	53,894,000	53,758,000

1/ Excludes Gramm-Rudman-Hollings reduction of $2,474,700 and proposed rescission of $3,661,300.

NATIONAL INSTITUTES OF HEALTH

National Institute on Aging

ALZHEIMER DISEASE

In a recent editorial in Science magazine, Dr. Caleb Finch of the University of Southern California is quoted as saying, "I would be surprised if the major new resources required for a serious attack on Alzheimer disease do not also benefit the basic neurosciences on the same scale as funding for cancer research has done for many areas of molecular, cell, and developmental biology." In fact, research on Alzheimer disease is so broad-reaching that it is already having an impact on basic neuroscience research; while at the same time, basic neuroscience and other research is shedding new light on Alzheimer disease.

How Common is Alzheimer Disease?

By most estimates, Alzheimer disease is the cause of serious confusion and forgetfulness in some 2.5 million American adults. This is five times the estimate that appeared in the literature 10 years ago when the National Institute on Aging (NIA) began its first studies in this area. Are there so many more victims now than then? Is there an Alzheimer epidemic?

Because aging is the principle risk factor associated with Alzheimer disease, the number of Alzheimer victims is growing at least as fast as the U.S. older population. But these latest estimates stand for more than just growing numbers of older people. They reflect a more sophisticated, if not yet perfected, approach to diagnosis; better training of health care professionals regarding the problems of old age; and the general public's greater awareness of Alzheimer disease and its symptoms.

According to NIA-supported experts at Harvard University, our current estimates of the number of Alzheimer victims may still be too conservative. Dr. Denis Evans and his colleagues at the East Boston Neighborhood Health Center have examined the residents of that Boston community and have found that more than 11 percent of the population over age 65 may be suffering from Alzheimer disease. This is double the frequently stated estimates.

When this study has been completed and verified by other studies, and diagnostic capabilities are further refined, we may be surprised to learn how many people are suffering from Alzheimer disease and are being quietly cared for by relatives and friends.

The Cost of Alzheimer Disease

According to the Alzheimer's Disease and Related Disorders Association, $35 billion was spent last year on the care of Alzheimer patients. This includes the costs of nursing home and other long-term medical care, but doesn't begin to account for the emotional and social costs of the disease.

NIA health economist Dr. William Cartwright has tallied some of the specific costs of Alzheimer disease, suggesting that $35 billion is just the tip of the iceberg. Dr. Cartwright and his colleagues, Dr. Lien-Fu Huang of Howard University in Washington, D.C. and Dr. Teh-wei Hu of Pennsylvania State University in State College, estimate that the special services required by dementia victims might cost more than $38 billion, with another $39 billion for what the investigators call indirect costs.

The investigators looked at how much money is spent on longer hospital stays, increased need for drugs, greater demands on staff time in nursing homes, special social services and other needs. A large portion of the cost of dementia—$27 billion—reflects the value of the time spent by relatives who care for Alzheimer patients at home.

This is the first time that anyone has calculated the costs of dementia. It is also the first time that anyone has put a value on the so-called "incalculable costs" of the disease. The $39 billion for indirect costs represents the investigators' estimate of the cost of relatives visiting patients in nursing homes, transporting patients for needed medical services, and premature death due to dementia. Dr. Cartwright cautions that these estimates may seem conservative because they include only the extra costs of medical care, rather than all the costs of medical care, for dementia victims.

The Diagnosis of Alzheimer Disease

There is no single medical test that can diagnose Alzheimer disease. The early symptoms of Alzheimer disease—forgetfulness, confusion, changes in mood and behavior—are also symptoms of a large number of other conditions. As a result, physicians who suspect Alzheimer disease use a variety of tests, including medical history, clinical examination, blood and other laboratory tests, pychological tests and radiologic scans. The diagnosis of Alzheimer disease is made only after all other possibilities have been excluded.

Nonetheless, we are better able to diagnose Alzheimer disease today than ever before. Physicians are more attuned to the various disorders that can mimic Alzheimer disease, and are more likely to detect them during medical examinations. Newer psychological tests have begun to focus more closely on the early and progressive signs of Alzheimer disease. And now, recent developments in radiology have provided diagnostic tools that can better visualize the working human brain.

At the Massachusetts General Hospital in Boston, NIA grantee Dr. John Growdon and his colleagues are using magnetic resonance imaging (MRI), a recently developed diagnostic tool, to examine patients with Alzheimer disease and other forms of dementia. For an MRI scan, the patient is positioned inside a magnetic field crossed by radio frequency waves. The magnetic field causes the body's abundant supply of hydrogen atoms (which are positively charged) to come into alignment; the radio waves then deflect them out of alignment. When the waves are turned off, computers measure the energy emitted as the atoms realign within the magnetic field. By a complex system of calculations, information is then generated on the concentration of matter as well as certain physical and chemical properties.

The technique is safe and painless. In some cases, MRI brain scans may even be superior to CT scans in that the images are crisper, they differentiate between white and grey matter and they can visualize deep areas of the brain not seen in CT scans. Because MRI can more accurately pinpoint tumors and other intracranial disorders, the scans are extremely useful to physicians in diagnosing patients' problems.

Dr. Growdon and his colleagues have found that the unique ability of MRI to distinguish the brain's white and grey matter allows it to pick up abnormalities that may indicate early multi-infarct dementia (dementia caused by a series of small strokes). It is the second leading cause of dementia in older people and is frequently confused with Alzheimer disease because of similar symptoms.

Whether NMR will be a valuable diagnostic tool for Alzheimer disease is difficult to predict since this technology is still in its infancy. In the meantime, however, Dr. Growdon and his colleagues are excited by their findings of white matter lesions in people who show no other sign of disease. If this is, indeed, an early indication of multi-infarct disease, diet and life style changes may prevent further damage.

As this research progresses, Dr. Growdon will be looking at those areas of the brain known to be affected in Alzheimer disease to see if changes in brain structure can be linked to changes in function as the disease progresses.

What Causes Alzheimer Disease?

The theories of what causes Alzheimer disease have matured in a rich atmosphere of research focused on the neuroscience of aging. The basic theories have not changed. Scientists still think that genetic factors; immunologic changes; unconventional virus-like agents; and environmental factors may all play a role in the development of Alzheimer disease. Nonetheless, more basic answers are being sought as to what causes the disease. NIA-supported scientists are examining the fundamental processes that underlie changes that take place in the brains of patients with Alzheimer disease.

At the Burke Rehabilitation Center in White Plains, New York, NIA grantee Dr. John Blass and his colleagues are doing research on enzyme activity, calcium transport, glucose metabolism and protein synthesis in an effort to reveal the events that precipitate neurotransmitter changes and even cell death in Alzheimer disease. Their search has led them to look at tissues, fluids, and cells outside the brain. Based on their results, they have speculated that Alzheimer disease is a systemic metabolic disease, not simply a neurologic disorder.

For some time, scientists have known that there is a drop in overall glucose metabolism in the brains of Alzheimer patients; in other words, the Alzheimer brain uses less energy. Dr. Blass and his colleagues looked at glucose metabolism in tissues taken from Alzheimer patients and found that there was an inherent abnormality in the cells' ability to break down glucose into energy. They also found a defect in calcium transport at the cellular level.

According to Dr. Blass, Alzheimer disease may be a neurologic disease with systemic manifestations or a systemic disease that shows itself primarily in terms of brain changes. This realization may alter the approach to studies of how the disease develops and how it can be diagnosed and treated.

Alzheimer and Pick Disease: A Common Cause?

Other research continues to alter our understanding of Alzheimer disease. At Harvard University, NIA grantee Dr. Dennis Selkoe has found a surprising similarity between Alzheimer disease and Pick disease, a rare, rapidly progressive dementia.

Alzheimer and Pick diseases have always been presumed to be distinct neurological disorders. Although victims of both diseases suffer disabling dementia, the neurofibrillary tangles and neuritic plaques that characterize Alzheimer disease are not found in the brains of individuals who had Pick disease. Only an autopsy can distinguish between the two diseases.

Earlier studies by other investigators had shown that both Alzheimer and Pick diseases affect the same parts of the brain. Research had even speculated that although the lesions of Pick and Alzheimer were different, they might be composed of the same abnormal proteins called paired helical filaments (PHF). Following these leads, Dr. Selkoe used a technique developed in his laboratory to study nerve cells from the brains of Alzheimer and Pick victims. He found that the PHF's once thought to be unique to Alzheimer disease were indeed located in the brain cells of Pick patients.

Dr. Selkoe speculates that Pick disease may be a variant of Alzheimer disease and that the two may share a common cause. This opens up a new field of investigation.

A Blood Test for Alzheimer Disease?

In addition to neurofibrillary tangles and neuritic plaques, Alzheimer disease is characterized by deposits of amyloid fibers in the brain's blood supply. Dr. George Glenner at the University of California, San Diego has isolated and analyzed the amyloid fibers circulating in the bloodstream of Alzheimer patients and found a unique protein not seen in healthy individuals. Interestingly, the same protein appears in the amyloid deposits of Down syndrome, representing a link between Alzheimer and Down syndrome. With NIA support, Dr. Glenner next plans to use monoclonal antibodies to take a closer look at this unique protein with the hope of isolating its precursor.

His work reveals yet another clue that Alzheimer disease is a systemic disorder, and may someday lead to a simple diagnostic test for the disease.

The Aluminum Story

When scientists first looked at the brains of Alzheimer patients, they found excessive levels of aluminum concentrated in dying brain cells. These findings led to fearful speculation by the public that Alzheimer disease could result from ingesting aluminum or using household products containing aluminum. Fortunately, epidemiologists have ruled out such a simple answer to what causes the disease, and our approach to studies of environmental risk factors has become much more sophisticated.

NIA grantee Dr. Bernardino Ghetti has confirmed that when the central nervous system is exposed to aluminum over long periods of time, the result is neurofibrillary degeneration and ultimately cell death. In his work at Indiana University School of Medicine in Indianapolis, Dr. Ghetti is beginning to elucidate the mechanisms by which aluminum causes nerve cell damage. He has found that aluminum binds to the protein calmodulin, impairing its ability to regulate calcium levels in the cell. Calcium is similar in structure to aluminum and is vital to the life of the cell but toxic in large quantities. According to Dr. Ghetti, the key to aluminum 's deadly effect on nerve cells may be this breakdown of calcium metabolism at the cellular level.

The Genetic Hypothesis

A discussion of possible causes of Alzheimer disease would not be complete without some reference to genetic studies. It seems apparent from our research thus far that the majority of Alzheimer victims don't inherit the disease from their parents. While there appears to be a familial form of Alzheimer disease in which the children of people with Alzheimer disease have a 50 percent chance of developing it later in life, it may be far more common for people to inherit a predisposition to the disease. In an NIA-supported study at the Bronx Veterans Administration Medical Center in New York, Dr. John Breitner has found that Alzheimer patients are much more likely than those without the disease to have a close relative with dementia. Another genetic research project is described in the NINCDS section of this report. Both of these studies lend support to the position that genetic factors play a significant role in Alzheimer disease.

The Treatment of Alzheimer Disease

Several times during the past year, the media have publicized major improvements in Alzheimer patients given experimental drugs. Each time, a closer examination has revealed that there is still a great deal of work to be done. Scientists now find it necessary to use a variety of tests to evaluate their patients' responses to new drugs, without knowing how reliable the tests results are. A pressing need is for a test that can be used to assess the potential of any drug.

At the Bronx Veterans Administration Medical Center in New York, NIA grantee Dr. Kenneth Davis has devised a simple test that focuses on the major symptoms of Alzheimer disease and can be used to evaluate patients in all stages of the disease. The test is brief, easy to administer, and can be used anywhere the patient is located. It evaluates such factors as memory, language, mood and behavior; it rates the majority of the items on a five point scale of severity so that subtle changes can be detected.

Dr. Davis and his colleagues originally designed a scale with 40 items. After more than a year of tests, they have pared the list to 21 items they believe are valid and reliable measures of any change in a patient's symptoms of Alzheimer disease.

It is hoped that the Alzheimer Disease Assessment Scale will be sensitive enough to measure the success of any future attempts to treat the disease.

National Institute of Neurological and Communicative Disorders and Stroke

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) conducts and supports extensive research to understand the progressive, irreversible brain deterioration of Alzheimer disease. Areas of intense research interest are changes in brain chemistry, cell death from viral infections or environmental toxins, and genetic susceptibility to the disease.

Changes in Brain Chemistry

A disruption in one of the brain's chemical messenger systems, the cholinergic system, has been implicated in Alzheimer disease. At The Johns Hopkins University in Baltimore, Maryland, NINCDS and NIA grantee Dr. Joseph Coyle and his colleagues have shown that one message pathway in the cholinergic system that deteriorates in the brains of Alzheimer victims also is destroyed in a rat model. This discovery might help explain why the brain's cortex and hippocampus, which lie at the end of this pathway, accumulate nerve fiber tangles and plaques characteristic of Alzheimer disease, and why Alzheimer patients lose short-term memory governed by the cholinergic system but retain the long-term memory maintained by other chemical messenger systems.

This year, Dr. Coyle simulated cholinergic system deterioration in rats using a chemical that damages only cholinergic neurons. His study suggested that memory loss in the rat model of Alzheimer disease may be reversible: animals with induced cholinergic damage eventually regained some of their short-term memory.

NINCDS grantee Dr. Marek-Marsel Mesulam and his colleagues at Beth Israel Hospital in Boston, Massachusetts, this year identified a distinct group of cholinergic neurons extending from the basal forebrain along cholinergic pathways and linking selected neurons in the basal forebrain with particular regions in the cortex. The investigators previously had demonstrated that changes in such cell groups can trigger the kind of brain dysfunction associated with Alzheimer disease. Studies of the newly discovered cell group show that these cells influence a region of the brain that transmits visual and other sensory information.

Epidemiological Factors

A team of American and Italian investigators this year reported on the largest case-control study of Alzheimer risk factors, completing a 3-year collaborative effort of the Italian National Research Council and the NINCDS. The findings indicated that people whose brothers or sisters have any form of dementia may be 11 times more likely than others to develop Alzheimer disease. The study also provided some support for earlier observations that severe head trauma may be a risk factor for Alzheimer disease, and that babies born to mothers over age 40 may be at greater risk for dementia later in life.

This study, carried out at seven Italian medical centers under the Science and Technology Agreement between Italy and the United States, did not support risk factors suggested by earlier, smaller case-control studies: family history of Down syndrome, previous thyroid disease, exposure to aluminum or other toxins, allergies, previous surgical procedures, habits of smoking or drinking wine, or certain personality traits. The results did suggest that diagnoses of Alzheimer disease may vary greatly according to the patient's socioeconomic status, probably because mental impairment is more noticeable in people whose education or life style reflects a certain degree of intellectual achievement.

In addition to their work on this project, NINCDS intramural investigator Dr. Bruce Schoenberg and his research team reported this year on the occurrence of Alzheimer disease among the 24,000 residents of Copiah County, Mississippi. This landmark study measured the incidence and prevalence of various neurological disorders in a racially mixed population. The results demonstrated that the rate of Alzheimer disease is similar among both blacks and whites. Furthermore, twice as many women as men had Alzheimer disease, and the number of Alzheimer patients increased with advancing age, from 1 percent among people aged 40 years and older to 7 percent among those 80 years and older. The range of other estimates of Alzheimer disease indicates that more research in different populations may be needed to establish firmly the incidence of the disease.

The Role of Infectious Agents

Since the late 1960's, some scientists have speculated that Alzheimer disease might result from a "slow virus" infection, which is caused by an infectious agent that resides within the body for years before producing devastating disease. Dr. Stanley Prusiner of the University of California at San Francisco—a grantee of the NINCDS and the NIA—first identified the "prion", which causes some slow infections, as well as a specific protein that is the major component of the prion. This year, Dr. Prusiner's research suggested that the prion protein comes from a larger protein present in both normal and infected cells. In normal cells, the larger protein is completely broken down by enzymes; in infected cells, a defective breakdown leaves the prion intact. According to Dr. Prusiner, this prion aggregates to form a fibrous structure that resembles certain filaments found in the brains of Alzheimer patients. Dr. Prusiner is now trying to determine what might happen to change a normal cell into an infected cell and why it appears that the larger protein behaves differently in infected cells than in normal ones.

Genetic Predisposition

In an NINCDS-funded study of 3,500 nursing home residents, Dr. Marshall Folstein at The Johns Hopkins University found evidence of an autosomal dominant pattern of inheritance in certain families with high rates of Alzheimer disease. This could mean that each child of a parent with the familial form of Alzheimer disease has a 50 percent chance of developing the disease in later life.

National Institute of Allergy and Infectious Diseases

The hypothesis that a slow-acting virus or other infectious agent is the cause of Alzheimer disease is based in part on the known transmissibility of certain other degenerative brain diseases in both humans and animals.

In the effort to understand the causes and mechanisms of Alzheimer disease, National Institute of Allergy and Infectious Disease (NIAID) scientists have sought to identify animal diseases with similar characteristics.

One animal model is scrapie, a slowly progressive neurologic disease of sheep and goats. Scrapie, which can be transmitted to a variety of animal species including mice, hamsters, and mink, is so named because stricken animals repetitively scrape against fence posts and trees. As the disease progresses, the animals degenerate steadily, become paralyzed, and die.

Scrapie infection is characterized by large fibril structures and neuritic plaques in brain tissue, features strikingly similar to pathologic findings in patients with Alzheimer disease. These plaques, which are somewhat like scars on the brain, are found in many chronic diseases, although none have been detected so far in diseases in which viruses have been proven to be the cause.

Purified samples of scrapie-infected tissue have been shown to transmit disease to healthy laboratory animals. Upon close examination, one protein—the prion protein mentioned earlier—has been found to predominate in the infected tissue.

Dr. Bruce Chesebro at NIAID's intramural Rocky Mountain Laboratories in Hamilton, Montana, has been studying the prion protein. He and his colleagues have discovered the genetic material for this protein in both healthy and scrapie-infected animals, indicating that the protein is probably a component of normal brain tissue.

Dr. Chesebro examined the brains and other organs of healthy and scrapie-infected mice, using a chemical probe designed to detect the messenger ribonucleic acid (mRNA) sequence that corresponds to the prion protein. Messenger RNA is the molecule that transmits the DNA message to the cell's cytoplasm where it directs protein synthesis. The mRNA sequences were found in tissues of both healthy and infected animals. In no case was the mRNA specific for scrapie-infected tissue.

Dr. Chesebro suggests that prions may simply be part of a healthy cell's structure, and some aspect of the infection causes the protein to bind together to form the deposits found in infected animals. In other words, accumulated protein may be the result of scrapie infection rather than the cause.

Dr. Chesebro's work does not explain the nature of the scrapie agent. His findings do make conceivable the theory that very small virus particles may be responsible for scrapie and other slowly developing diseases.

Division of Research Resources

Patients with Alzheimer disease often have a marked reduction in cells that produce acetylcholine, one of the neurotransmitters that allows nerve fibers to send electrical messages. The loss of these cells may be a cause of some symptoms of the disease. In an effort to increase nerve cell activity associated with acetylcholine, Dr. Richard Mohs and his colleagues at the Mount Sinai School of Medicine in New York City recently gave 12 patients oral doses of the drug physostigmine, which mimics the action of the neurotransmitter. The tests were conducted in the Mount Sinai General Clinical Research Center (GCRC), one of 78 such centers supported by the Division of Research Resources. More than 30 percent of the extramural inpatient research care funded by NIH takes place in these centers.

Previous studies at the Mount Sinai GCRC and other medical centers had indicated that intravenous use of the drug temporarily improved the memory of Alzheimer patients. Uniform levels of physostigmine, however, were difficult to maintain due to its short (30-minute) half-life in the bloodstream. Other tests had indicated that a constant level of the drug may be achieved if it is taken orally every two hours. The investigators found varying improvements in the memory, sleeping patterns, and behavior of Alzheimer patients during two studies with the drug.

In the first study, designed to find the most effective dose of physostigmine, 10 of the 12 patients significantly improved their scores on the Alzheimer Disease Assessment Scale, the evaluative test described earlier. But in a followup test that compared a placebo with the physostigmine dose believed to be most effective, only three patients showed significant improvement using physostigmine; four others improved slightly.

According to Dr. Mohs, drugs that increase acetylcholine activity may help some patients with Alzheimer disease, but further research is needed to identify safer, longer-acting drugs.

Future Directions for Research

NIH will continue to support research on Alzheimer disease. Studies will focus on analyzing the protein chemistry of normal and abnormal brain structures; developing monoclonal antibodies for specific brain proteins; looking at brain enzymes, particularly those related to oxidative metabolism and neurotransmitter synthesis; and measuring the effects of toxins, infectious agents and genetic factors on brain degeneration. Research will continue on ways to make an early and accurate diagnosis of Alzheimer disease, and to use improved diagnosis as the basis for establishing multinational epidemiologic studies. Through a cooperative arrangement with NINCDS, NIA will provide cells from definitely diagnosed Alzheimer cases to investigators studying the molecular biology and genetics of the disease. Research will expand on the behavioral and social aspects of the disease, including how families cope under such tremendous stress.

In 1984, the NIA was given authority by the U.S. Congress to establish Alzheimer Disease Research Centers, 10 of which are currently being funded. The most exciting opportunity for future research on Alzheimer disease rests in the potential of these centers to act as a network for sharing new ideas as well as research results. Already, the center directors are communicating about such matters as joint patient registries; shared data, tissue, and brain banks; and standardized diagnostic criteria. The Alzheimer Disease Research Centers share a common goal: to enhance research on the disease by providing the resources and environment for collaborative studies among many scientists from many different disciplines. The long-term reward may be a way to cure and possibly prevent Alzheimer disease. The immediate payoff will be better care for more of its victims.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute of Mental Health

Family Stress and the Care of Alzheimer's Disease Victims

The 1986 Report of the House Appropriations Committee (N 99-289), dated September 26, 1985, page 83 makes the following statement:

> "The Committee is pleased that the Institute has initiated a program focusing on the family stress problems relating to the care of victims of Alzheimer's disease and the development of family care and service delivery models. The Committee expects that these initiatives will be continued in FY 1986 and the Institute will submit a report on these initiatives by February 15, 1986."

This Report is submitted in response to the Committee's request.

In April 1985 the National Institute of Mental Health issued a specialized Research Grant Announcement, "Research on Family Stress and the Care of Alzheimer's Disease Victims" soliciting applications on this topic. Applications will be accepted under this specific program through FY 1985 and 1986.

The specialized announcement solicits applications which focus on the generation of systematic information on: the nature, consequences, and interplay of stress associated with caregiving; factors associated with understanding and enhancing family support; the identification, treatment, and management of excess disability in Alzheimer's Disease(AD) patients and strategies to maximize their functional level at all stages of the disease; the prevention of psychopathology and the promotion of mental health among family caregivers; and research on the design and delivery of services providing treatment and clinical interventions for individuals with AD and for the family members who care for them.

In FY 1985, six (6) projects were funded with total costs of $841,257.

The studies currently underway in this area include:

R01 MH40480	$151,089	Caring for Demented Spouses: Crisis vs. Adaptation Rachel A. Pruchno This prospective longitudinal study is assessing the differential impact which chronic dementias cause in the caregiving spouse in order to characterize those factors which may influence the intensity, duration, and frequency of negative consequences of coping with the disease process. This study is expected to provide new information relevant to identifying with specific groups of spouse caregivers who are at risk for dysfunction.

R01 MH35360	$141,218	Caring for Elders and Mental Health of Family Members Walter S. Poulshock Benjamin Rose Institute This panel study is designed to look at family decisionmaking in the context of home caregiving to an impaired older relative. This research investigates the way in which families resolve problems in relation to major changes in the AD patient's status on care arrangements. The caregiving situation is examined as a process in which stress and the effects of stress have consequences for the mental health of all family members.
R01 MH37292	$182,345	Senile Dementia Patients: Mental Health of Caregivers M. Powell Lawton Philadelphia Geriatric Center This research is investigating the mental health problems associated with caregiving to clinically impaired senile dementia patients, and patients without dementia. This research has a strong focus on the quality of life of caregivers and on community dwelling and institutionalized AD patients.
R01 MH35352	$230,418	Patient Care, Sibling Relationships and Mental Health Elaine M. Brody Philadelphia Geriatric Center This research is studying sibling relationships in situations in which a widowed elderly mother needs help and has two or more adult children. The aim of the research is to obtain information on the apportionment of parent care responsibilities within the family and to examine both problems and positive factors in sibling relationships related to caretaking responsibilities for elderly parents.
P50 MH40041	$ 24,000	Psychosocial Component of Clinical Research Center for the Study of Senile Dementia Jerome A. Yesavage Stanford University Two preliminary studies are being conducted: The first is an evaluation of the nature and intensity of psychological problems experienced by caregivers of AD patients, and the nature of coping strategies used by them. The second project is an intervention study focusing on the efficacy and appropriate timing of various psychotherapies given to AD spouse caretakers who suffer from major depressive disorders.

R01 MH33779 $112,187 Stress Vulnerability in Alzheimer Patient's Families
Joseph Becker
University of Washington

This study is examining the vulnerability to, and incidence of, depression among spouse-caregivers of Alzheimer's disease.

These grants being funded by the National Institute of Mental Health examine the problems of family caregivers from a variety of different perspectives and disciplines. Findings from these studies will lead to improving our understanding of how families make decisions in relationship to the major aspects of caregiving such as institutionalization and apportionment of care, enhance the ability of support systems to identify vulnerable caregivers at risk for developing stress related dysfunction, and establish the efficacy of various interventions designed to alleviate caregiver distress. Through the complementary approaches undertaken by these grants it is anticipated that they will achieve greater gains in the application of research findings to practice than if a single protocol were followed.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

ALZHEIMER'S DISEASE

According to the 1984 National Hospital Discharge Survey, an estimated 15,000 patients were discharged from short-stay hospitals in the United States with a first-listed diagnosis of Alzheimer's Disease. The average length of stay for these patients was 9.9 days. In addition to those patients with a first-listed diagnosis of Alzheimer's Disease, an estimated 59,000 patients were discharged with a secondary diagnosis of Alzheimer's Disease.

Data on Alzheimer's Disese is unavailable from the Health Interview Survey at this time. On the 1984 supplement on aging Alzheimer's was included on the condition list and data should be available once 1984 is released.

Numbers of deaths reported on the death certificate for Alzheimer's disease have increased markedly in recent years. In 1979, a total of 857 deaths from this cause were reported in mortality data from NCHS. By 1983, the number had increased by over five times to 4,434.

OFFICE OF HUMAN DEVELOPMENT SERVICES

Administration of Aging

Alzheimer's Disease Initiative

In FY 1984, AoA implemented a multi-year special initiative for the development of support groups for families of older persons with Alzheimer's disease. The purpose of this effort is to increase the support and assistance available to families in coping with the problems associated with the disease.

To implement the initiative, AoA developed a strategy for collaboration between the AoA Regional Offices and the Long-Term Care Gerontology Centers to train State Unit and Area Agency personnel about Alzheimer's disease and the development of community-based support groups. Subsequently, State Units and Area Agencies have been asked to replicate this training as appropriate throughout their States. To assist State Units and Area Agencies in carrying out the initiative, a comprehensive technical assistance package was developed and, to date, nearly 10,000 copies of this material have been distributed nationwide.

More than 5,000 persons who work with older persons have been trained including staff of State Units and Area Agencies on Aging, service providers, and staff of health care programs. Forty-one (41) States have made a commitment to undertake significant State activity to support this effort. Twelve States have formed State level task forces to develop recommendations for changes in State programs and to improve services to older persons with Alzheimer's Disease and their families. Seven of these States have appropriated State funds to support new activities such as day care, respite care, and other such services. Many States have instituted ongoing training programs to help staff understand the needs of Alzheimer's patients.

Another significant undertaking in support of AoA's Alzheimer's Disease Initiative was the funding in FY 1985 of twelve (12) research and demonstration projects aimed at: 1) increasing public awareness and understanding of the disease; 2) demonstrating and testing models for family support groups, particularly in rural areas; and 3) developing innovative approaches to respite care and caregiver training.

Alzheimer Disease Support Network

AoA made twelve new awards to projects designed to find more effective ways of serving Alzheimer's Disease victims and their families. These research efforts paralleled the HHS priority to find the cause of and the cure for Alzheimer's Disease.

Five projects will demonstrate and test models of caregiver training, focusing on:

- the effectiveness of legal counseling;
- issues of concern to rural caregivers;
- the efficacy of behavioral programming techniques for Alzheimer's patients;
- telephone support networks both as a means of instruction and a source of emotional peer support for Alzheimer's caregivers; and
- church-based counseling services.

Three projects will demonstrate innovative approaches to providing respite care for family caregivers while two other projects are concerned with public awareness and understanding of the disease.

One grant was awarded to develop and implement model family support groups for rural areas. Another will develop a State residential resource center for Alzheimer's Disease victims.

ARTHRITIS AND RELATED MUSCULOSKELETAL DISORDERS

Obligations

	1983 Actual	1984 Actual	1985 Actual	1986 Appropriation	1986 Available After Sequestering	1986 Revised Estimate	1987 Estimate
Public Health Service:							
National Institutes of Health:							
National Institute of Arthritis and Musculoskeletal and Skin Diseases.........	$51,065,000	$56,783,000	$65,623,000	$69,300,000	$66,300,000	$65,400,000	$63,800,000
National Institute of Diabetes and Digestive and Kidney Diseases..	1,809,000	2,918,000	3,444,000	3,340,000	3,150,000	3,080,000	3,020,000
National Cancer Institute........	879,000	997,000	811,000	900,000	880,000	750,000	730,000
National Heart, Lung and Blood Institute........	1,634,000	1,728,000	1,744,000	1,870,000	1,790,000	1,764,000	1,695,000
National Institute of Dental Research.........	3,087,000	3,465,000	3,700,000	3,850,000	3,684,000	3,684,000	3,650,000
National Institute of Neurological and Communicative Disorders and Stroke..........	1,142,000	3,206,000	3,536,000	3,868,000	3,702,000	3,616,000	3,578,000

ARTHRITIS AND RELATED MUSCULOSKELETAL DISORDERS (continued)

Obligations

	1983 Actual	1984 Actual	1985 Actual	1986 Appropriation	1986 Available After Sequestering	1986 Revised Estimate	1987 Estimate
Public Health Service:							
National Institutes of Health:							
National Institute of Allergy and Infectious Diseases.........	8,176,000	11,536,000	12,845,000	13,127,000	12,544,000	12,498,000	12,320,000
National Institute of General Medical Sciences.	1,026,000	1,003,000	1,230,000	1,250,000	1,250,000	1,250,000	1,250,000
National Institute of Child Health and Human Development......	1,299,000	1,552,000	1,808,000	1,900,000	1,800,000	1,800,000	1,800,000
National Institute of Environmental Health Sciences..	72,000	90,000	0	0	0	0	0
National Institute on Aging.........	2,058,000	2,041,000	1,649,000	1,862,000	1,782,000	1,745,000	1,701,000
Division of Research Resources........	3,220,000	3,551,000	4,080,000	4,155,000	3,976,000	3,976,000	3,534,000
Total, NIH....	75,467,000	88,870,000	100,470,000	105,422,000	100,858,000	99,563,000	97,078,000

NATIONAL INSTITUTES OF HEALTH

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

ARTHRITIS, RHEUMATIC DISEASES, AND RELATED DISORDERS

Arthritis can affect not only the joints but also other connective tissues of the body. These tissues include important supporting structures such as muscles, tendons, and ligaments, as well as the protective coverings of internal organs. Strictly speaking, the word "arthritis" means joint inflammation, although it is often used more broadly to indicate any joint or connective tissue disorder. These disorders--of which there are more than 100--are also frequently referred to as the rheumatic diseases.

At present, rheumatic diseases affect more than 37 million Americans--approximately one in seven. Arthritis, the Nation's number one crippler, can afflict people of all ages, including children and adults in the prime of life.

A full understanding of many forms of arthritis remains elusive, but research has brought us closer to answering important questions about these disorders and, in some cases, has provided effective means to treat, control, or prevent them, or to reduce their harmful effects.

Major advances in arthritis research over the years include:

- identifying the cause of and developing a treatment for Lyme disease, a form of arthritis that has been found to be caused by a newly recognized infectious agent.
- improved survival rates for systemic lupus erythematosus (SLE or lupus), an inflammatory disease of the connective tissue, that can affect many parts of the body, including the joints, skin, and internal organs.
- the finding that additional calcium and estrogen replacement in postmenopausal women may halt or retard the progress of osteoporosis. This disease, characterized by decreased bone mass, causes an estimated 1.3 million fractures annually in people 45 years of age or older.
- remarkable clinical advances in total hip joint replacement that have led to the development of replacements for other diseased or damaged joints that are sources of pain and disability. Today, abnormal alignment of joints can be corrected, and tendons and ligaments can be repaired.

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) leads and coordinates the Federal biomedical research effort against the many forms of arthritis and related disorders. Through its extramural programs of grants and contracts, the Institute supports research projects at universities, medical schools, and other research institutions throughout the country. In addition, NIADDK conducts an intensive intramural research program at the Warren G. Magnuson Clinical Center of the National Institutes of Health.

NIADDK RESEARCH HIGHLIGHTS

Although medical science has not yet found a cure for many types of arthritis, significant progress has been made through both basic and clinical investigations.

Rheumatoid Arthritis

The major crippling disorder among the chronic rheumatic diseases, rheumatoid arthritis (RA) affects more than 7 million Americans. This chronic inflammatory disease of unknown cause affects twice as many women as men. The primary target of rheumatoid arthritis is the synovium (joint lining). This tissue, which normally should be smooth and shiny, becomes inflamed, painful, and swollen. Rheumatoid arthritis is also a systemic disease that can cause general symptoms such as weakness, fatigue, and loss of appetite. RA tends to be both chronic and irregular, and can be very disabling.

In research on new effective therapies for rheumatoid arthritis, NIADDK grantee Dr. Michael E. Weinblatt and colleagues at Beth Israel Hospital in Boston have shown that low doses of methotrexate--the anticancer drug used to treat patients with psoriasis and psoriatic arthritis--suppress the inflammation of rheumatoid arthritis. Twenty-eight patients with severe rheumatoid arthritis who had not responded to conventional therapy received either methotrexate or a placebo for 24 weeks. Although no remission of the arthritis was reported, the methotrexate group had significant reductions in the number of swollen joints, as compared to the placebo group. These findings corroborate results from an NIADDK multicenter study led by Dr. John Ward at the University of Utah in Salt Lake City.

A new animal model for rheumatoid arthritis may provide new insights into the causes of this disease. Researchers at the University of Alabama in Birmingham led by Drs. William J. Koopman and Francis X. O'Sullivan have developed an animal model that spontaneously develops a disease resembling human rheumatoid arthritis. Their studies of these mice have suggested that joint destruction can occur before there is any evidence of joint inflammation.

A substance found in the nervous system may play an important role in promoting the inflammatory component of arthritis. In a study of rats with an experimentally induced arthritis similar to rheumatoid arthritis in humans, grantee Dr. Jon Levine and associates at the University of California at San Francisco and also at Massachusetts General Hospital in Boston found that the severity of arthritis can be attributed to actions of "substance P" in the affected joint. Substance P, produced by nerve endings, is involved in transmission of pain signals. The researchers believe that measures designed to block and reduce substance P levels in joints may effectively combat both inflammation and tissue destruction.

Osteoarthritis

More than 16 million Americans are afflicted with degenerative joint disease or osteoarthritis. This most common form of arthritis primarily affects the cartilage of the joint, causing it to fray, wear, ulcerate, and, in extreme cases, to disappear, leaving a bone-on-bone joint. At the edges of the joint, spurs may form. Disability most often results from osteoarthritis of the weight-bearing joints (knees, hips, and spine).

To focus more attention on research on osteoarthritis, a workshop was held in July 1985, sponsored by the NIADDK, the National Institute on Aging, and voluntary health organizations, including the American Academy of Orthopaedic Surgeons and the Arthritis Foundation. Experts in epidemiology, anatomy and pathology, biochemistry, biomechanics, inflammation, and clinical medicine assessed current knowledge of osteoarthritis and suggested research directions.

Investigators are using a variety of approaches to understand better why and how osteoarthritis occurs. NIADDK grantee Dr. Nancy Lane and associates at Stanford University in Stanford, California, are studying 550 members of the Over 50 Runners Club who have run an average of 9,983 total miles each. The researchers have compared a subset of the runners with a group of nonrunners in the same age range. Preliminary results indicate that running does not seem to play a role in the development of osteoarthritis. However, running does foster an increase in bone density, according to the study.

Juvenile Arthritis

Although arthritis is commonly viewed as an affliction of adults, an estimated 250,000 children in the United States are also afflicted. The first cooperative medical project on the treatment of children with arthritis was conducted recently in both the United States and Russia. This study was designed to evaluate the safety and effectiveness in children with arthritis of two powerful slow-acting drugs ordinarily used in adults with arthritis. NIADDK grantee Dr. Earl Brewer at Texas Children's Hospital, Houston, reported that although more than half of the children taking these compounds--penicillamine and hydroxychloroquine (an antimalarial drug)--improved, a similar number of patients taking placebo and milder nonsteroidal anti-inflammatory drugs also improved. Additional studies in children with rheumatoid arthritis are already under way to examine the therapeutic effect of a new oral gold compound, auranofin.

Lupus

According to the Lupus Foundation of America, there are more than 500,000 people, primarily young women, with the disease. The exact cause of lupus is unknown, but evidence suggests that the disease may result from a disorder in the body's production of antibodies (proteins that fight invading organisms). In lupus, abnormal antibodies are produced that react against the patient's own tissues.

Researchers led by Dr. David Wofsy, University of California, San Francisco, are studying abnormal immune responses in lupus. In studies of mice with lupus, they found that the course of the disease can be improved through the use of highly specific monoclonal antibodies that can remove a subset of immune cells known as helper T cells. The researchers hypothesize that these helper T-cells may promote the abnormal immune reactions in lupus, and that ultimately anti-T-cell antibodies may be able to retard SLE development in humans.

In studies of the genetic aspects of lupus, Dr. Betty Diamond, a grantee at Albert Einstein College of Medicine, Yeshiva University, New York, is using monoclonal antibodies to analyze antibodies to DNA, the substance of heredity. Antibody to native DNA is considered to be specific for lupus and is found in most lupus patients. In studies of familial lupus, she and her colleagues have shown that there may be a genetic predisposition or an inherited defect that causes genes to encode anti-DNA antibodies.

Scleroderma

Scleroderma is characterized by excessive deposits of the structural protein collagen in the skin and various other organs such as the heart, kidneys, lungs, and gastrointestinal tract. These deposits can cause thickening and hardening of the affected organs. Effects of the disease range from mild to life-threatening.

NIADDK grantee Dr. Sergio A. Jimenez and associates at the University of Pennsylvania, Philadelphia, are studying the usefulness of gamma interferon produced by recombinant DNA technology in treating patients with scleroderma. (Gamma interferon is one form of interferon, a protein made by the body's immune system to help combat certain diseases. Skin cells were removed from patients who had had active scleroderma for less than 1 year and from normal persons.

Scleroderma cells showed increased collagen production when compared with normal cells. When the researchers added gamma interferon to both cell lines, all cells showed a reduction of collagen. These results indicate that gamma interferon may provide a possible treatment for patients with this incurable disease.

Orthopedic Research and Related Diseases

Back Disorders

Low back pain is a major medical disorder that affects 50 to 80 percent of the United States population and causes an economic burden thought to exceed $10 billion annually. Back injuries due to improper lifting and handling of materials are a significant cause of work related disability, and account for a large amount of workers' compensation expenditures in the United States.

Investigators led by Dr. Matthew Liang at Boston's Brigham and Women's Hospital are studying how low back injuries can be prevented at the worksite by evaluating lifting practices of more than 4,500 Boston postal workers and their supervisors. The ultimate goals of the study are to reduce the incidence of lifting-related back injuries and the subsequent loss of work time.

While the above study relates primarily to injuries associated with the manual handling of materials, grantees Drs. Ian Stokes at the University of Vermont, Burlington, and Vijay Goel at the University of Iowa, Iowa City, are studying how repetitive mechanical loading on joints, bones, ligaments, tendons, and muscles of the back relate to the development of osteoarthritis, fractures, and other musculoskeletal injuries.

Osteoporosis

Osteoporosis, a major health problem, affects an estimated 15 to 20 million Americans. According to a recent report by Dr. Jennifer Kelsey, Yale University, New Haven, Connecticut, the total cost of osteoporosis and osteoporotic fractures in 1983 was an estimated $6.1 billion in the United States.

Researchers led by Dr. B. Lawrence Riggs at the Mayo Clinic in Rochester, Minnesota, recently compared the effects of menopause-caused estrogen deficiency to the effects of aging on bone loss. The researchers measured bone density in three groups of women: normal women in their early fifties at or before menopause (perimenopausal); normal postmenopausal women in their early seventies; and women of average age 54 who had undergone bilateral oophorectomy (surgical removal of both ovaries) 15 to 25 years earlier. The scientists found the same amount of bone loss in the oophorectomized women in their fifties as in postmenopausal women in their seventies. Both groups had significant bone loss compared to that of the perimenopausal women in their fifties. According to Dr. Riggs, estrogen deficiency, not aging, is the predominate cause of osteoporosis during the first two decades after natural menopause.

A common feature of osteoporosis is crush fractures of the vertebrae (the bony segments of the spine). Dr. Edmund Y.S. Chao and associates at the Mayo Clinic, Rochester, Minnesota, have developed a new biplanar X-ray method to measure and monitor geometric shape changes in the vertebrae of osteoporotic patients. Information from the X-rays is fed into a computer for calculation of vertebral configuration and for future comparison. The researchers said that it is important to quantitate vertebral changes accurately so that they can be related to the progression of the disease and the efficacy of treatment.

Osteogenesis Imperfecta (OI)

OI, an inherited disease, is characterized by fragile bones that fracture easily. Many people with the disease have multiple fractures throughout their lifetimes. Some children are born with fractures; others have their first fractures within a few months or years after birth.

A defect in collagen is generally accepted as a major factor in the development of OI. Researchers led by Dr. Darwin Prockop at Rutgers Medical School in Piscataway, New Jersey are using new technology (cDNA probes) to advance understanding of the molecular defects in the genes that determine collagen structure. In many patients with OI, the collagen fibers are malformed and misoriented. The researchers hope to identify possible gene defects in both parents and offspring, even before birth, and to develop methods to replace defective collagen genes.

Because OI bone is so fragile, the most common method of treatment is to reinforce it with a supporting rod that keeps the bone straight. In order to evaluate how much force can be applied to the bone and utilize the best method to strengtnen it, Dr. Peter Frasca and colleagues at Thomas Jefferson University, Philadelphia, have developed a new procedure to evaluate mechanically OI bone as compared to normal bone.

Exercise Pathophysiology

With growing national interest in exercise and fitness, new efforts are being directed toward understanding the responses of the body to various forms of exercise and physical training.

Dr. Ronald Terjung and associates at Upstate Medical Center, Syracuse, New York, are studying the biochemical and physiological influences of exercise training on muscle. Muscle performance is influenced by its type (fast- or slow-contracting) and its biochemical capacity for oxygen consumption. Muscle fatigue and its recovery vary in different types of muscle. Slow-conracting muscles, for example, recover from fatigue in less than 1 minute. In contrast, fast-contracting muscles require approximately one hour to recover. Dr. Terjung and his team have found that as a result of conditioning, fast muscles convert to slow muscles and recover from exercise more rapidly. This finding helps to explain the increased resistance to fatigue in well-trained athletes.

Knowledge gained from these basic studies of muscle physiology may eventually lead to the optimal rehabilitation programs, and to more efficient training programs for athletes.

As increasing numbers of children are involved in strenuous and competitive programs such as long-distance running, a potential concern is the long-term effect on growing bones and joints. Dr. Vittorio Pedrini-Mille and associates at the University of Iowa, Iowa City, recently completed a study to determine the effects of strenuous exercise on young knees. Researchers chose the chicken as the research model because chicken menisci (shock absorbing tissues within the knee) are similar to those of humans. The scientists found no ill effect on menisci of growing chickens who were put on a six-week treadmill-running regimen and no significant difference between the running animals and their sedentary controls.

New Developments in Joint Replacements

Total replacement of severely diseased or injured joints in the body has become a common and successful orthopedic treatment for arthritis, fractures, and related conditions. An NIH Consensus Development Conference on Total Hip Joint Replacement reported a 90 percent success rate 10 years after implantation. However, after many years, failures of the prosthesis due primarily to loosening have become increasingly common. Loosening of the implant is often accompanied by resorption of bone adjacent to the surgical cement. Researchers led by Dr. Myron Spector at Emory University, Atlanta, Georgia, are studying the use of cementless attachments of hip prosthesis. The most common approach is the use of porous materials to permit bone to grow into the stem of the prosthesis and thus provide a more permanent attachment than cemented devices.

Another approach to the problem of loosened hip joint replacements is the use of computer modeling to reconstruct mathematically the exact geometry of a particular femur (thigh bone). Researchers led by Dr. Peter S. Walker at Brigham and Women's Hospital, Boston, in their studies of cadaver femurs, showed that implanting an "exact-fit" prosthesis produced close to normal bone stress with minimal micromotion (motion between implant and bone). The scientists are beginning to apply this valuable information to custom-design of hip implants for younger patients, those with abnromal bone shapes, or those who had a prosthesis "fail". Similar techniques are also being applied to the design of knee joint replacements.

National Cancer Institute

In rheumatoid arthritis, tissue from the lining of bony joints proliferates and destroys the cartilage, bone, and tendons of the joints.

At the Dartmouth-Hitchcock Medical Center in Hanover, New Hampshire, Dr. Constance Brinckerhoff and colleagues, with support from the National Cancer Institute and the NIADDK, have been studying how retinoids--a family of compounds, including both natural and synthetic forms of vitamin A--inhibit collagenase production. Collagenase, an enzyme produced by connective tissue, is believed to play a role in rheumatoid arthritis. Dr. Brinkerhoff has found that, in animals and in animal cells grown in the laboratory, retinoids inhibit the production of collagenase even in the presence of factors that usually increase enzyme production.

In other work on growth factors, Dr. Brinckerhoff has looked specifically at the role of transforming growth factors in arthritis. Transforming growth factors play a role in turning normal cells into malignent ones but are found also in embryonic and some normal tissues. Dr. Brinckerhoff and colleagues have shown that the addition of transforming growth factors to laboratory cultures of normal cells from joints and connective tissue caused the cells to grow rapidly and pile up in a pattern characteristic of cultured human rheumatoid arthritis cells. This finding also applies to other cells in the joints that may play a role in rheumatoid arthritis.

Dr. Brinckerhoff's group has also reported that gamma-interferon produced by recombinant DNA technology increased cell division in cultures of normal cells from joints. This activity was enhanced by the anti-inflammatory drug prednisolone but blocked by the addition of a retinoid. Because gamma-interferon is secreted by white blood cells called T-cells, which are found in inflamed arthritic tissues, these findings may be relevant to the treatment of rheumatoid arthritis.

National Institute of Dental Research

The National Institute of Dental Research (NIDR) conducts and supports research related to arthritis because certain dental problems, such as periodontal diseases, have factors in common with diseases of the joints such as arthritis. In addition, the NIDR investigates chronic, acute, and inherited disorders of the human skeletal system.

NIDR intramural scientist Dr. Sharon Wahl is investigating why the tissues of arthritis patients are susceptible to chronic inflammation. Her studies of patients with chronic rheumatoid arthritis sho that their monocytes (blood cells that surround and kill infection-causing agents) do not migrate as they normally would toward inflammatory stimuli. Dr. Wahl has also discovered that, in a subpopulation of these patients, the cells responsible for inflammation in the tissue surrounding joints produce excess amounts of lymphocyte derived chemotactic factor, an agent that attracts monocytes. When the monocytes reach the inflamed joint, they in turn release several agents that enhance and perpetuate inflammation. One of these agents is fibroblast activating factor (FAF), a product of activated T-cells. FAF stimulates the development of fibrous tissue, which in turn, causes the release of prostaglandins and collagenase, which cause the degeneration of the joint. Dr. Wahl is now studying FAF in an effort to understand how rheumatoid arthritis develops. In collaboration with NIADDK scientists, Dr. Wahl has demonstrated that the development of erosive polyarthritis and hepatic granulomas (tumor-like masses of cells due to chronic inflammation) in rats treated with bacterial cell walls is dependent upon T cells. Rats treated with the T cell inhibitor, cyclosporin A, and athymic rats that are deficient in T cells do not develop chronic inflammatory arthritis or granulomas.

In studies of how genes regulate the development and function of connective tissue, NIDR intramural scientists Drs. Yoshihiko Yamada and John Termine and their colleagues have isolated DNA clones for some of the genes that produce cartilage and bone. This approach has been useful in determining the structure of cartilage and bone components. Molecular probes such as these can be used to measure levels of both collagenous and noncollagenous bone components in normal, developing and diseased skeletal tissue. Studies are also under way to inject collagen genes into mouse embryos that lack cartilage collagen and to incorporate cartilage collagen DNA into degenerating and normal cartilage cells. These molecular biology studies are essential for understanding the genetic basis of metabolic diseases of cartilage and bone, and may eventually lead to strategies for their diagnosis and treatment.

Proteoglycans are agents that are essential to the cushioning function of cartilage. NIDR intramural scientist Dr. Vincent Hascall and his associates are investigating both the chemical and physical properties and the biosynthesis of proteoglycans and other cartilage components in cell and tissue systems. In particular, he is studying how the components interact with each other, as well as what regulates the synthesis and turnover of the proteoglycans. Dr. Srinivasan Chandrasekhar, an NIDR scientist, has identified a collagen binding protein that regulates the size of the collagen fibers in cartilage. These studies have significant bearing on degenerative diseases such as arthritis, in which the early stages of which result in degradation and altered synthesis of cartilage.

NIDR's Dr. Valerie Horn and colleagues have been using monoclonal atnibodies to develop an assay for levels of chondronectin in blood. Chondronectin is a glycoprotein which, in cartilage, binds the cells to the surrounding matrix through interactions with the collagen and proteoglycans. Early data suggest that such a test will be a valuable diagnostic tool for measuring the metabolism of cartilage, and perhaps for identifying cartilage disease in the early stages.

In another NIDR intramural investigation, Dr. Haridara Reddi is studying the local and systemic control of bone development by bone matrix substances. He has identified and characterized the factor in bone matrix that is responsible for the formation of new bone. By learning more about how bone heals itself when fractured, scientists may discover ways to accelerate the healing process as well as determine how degenerative disease undermines the normal healing process.

Dr. Pamela Robey, NIDR intramural scientist has been investigating how serum from young and aging human individuals affects bone cells isolated either from young or old persons. Her studies demonstrate marked metabolic changes in bone cells as aging occurs. Such studies provide models for investigating molecular mechanisms operative in both bone degeneration and the aging processes.

National Institute of Neurological and Communicative Disorders and Stroke

In addition to studies of the central nervous system, the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) supports research on the interaction of the nervous system with the normal and abnormal function of the neuromuscular and immune systems. These studies seek basic information on how muscles, joints, nerves, and other neuromuscular components function in relation to each other, knowledge that may lead to a better understanding of some forms of arthritis.

Dr. Marinos Dalakas, an NINCDS intramural scientist, is investigating the structure and electrophysiological function of cells to determine the effects of aging on neuromuscular systems. Dr. Dalakas has identified structural changes in the muscles of older invididuals that may be similar to changes caused by arthritis. He has also found metabolic or immune abnormalities in the muscles, nerves, brains and spinal fluids of patients with polyneuropathy and amyotrophic lateral sclerosis, diseases, like arthritis, that are characterized by muscle weakness.

NINCDS intramural scientist Dr. Edward Oldfield is studying Cushing's disease, a disorder of the body's hormone secreting system caused by pituitary tumors. Cushing's disease resembles arthritis in its characteristic muscle weakness. Dr. Oldfield, in collaboration with investigators in Dr. Lynn Loriaux's laboratory in the National Institute of Child Health and Human Development (NICHD), is studying how chemical "releasing factors" in the brain's hypothalamus influence the release of hormones in the pituitary gland. Improved understanding of this process should help scientists develop new therapies for diseases affecting neuromuscular function.

Other NINCDS-supported studies focus on the treatment of chronic pain, another primary symptom of arthritis. This year, Dr. Judith Turner, a grantee at the University of Washington in Seattle, began an evaluation of two methods for treating chronic back pain. The first method combines training in relaxation techniques with teaching patients to recognize emotional factors affecting pain. The second combines exercise with instruction on how to modify behavior to reduce pain. Findings from these studies could apply to all types of chronic pain patients, including those who suffer from arthritis.

At Case Western Reserve University in Cleveland, Ohio, NINCDS grantee Dr. Terrone Rosenberry is studying the structural and biosynthetic relationships of several forms of the enzyme acetylcholinesterase (AChE). Dr. Rosenberry has found that the AChE found in neuromuscular tissues around joints is accompanied by a material similar to collagen.

The AChE found in other muscle membranes has no collagen. Dr. Rosenberry plans to analyze the amino acid sequence of human red blood cell AChE and compare it with other known types of AChE to learn more about how the neuromuscular system works.

NINCDS grantee Dr. Peter Grigg, at the University of Massachusetts Medical School in Worcester, is studying normal and deformed collagen structure in rats to determine its mechanical relationship to other molecules in joints. In another animal study, Dr. Grigg is investigating how neurons carry messages to the knee joint. His work will help explain what factors are involved in the body's response to stimuli.

National Institute of Allergy and Infectious Diseases

Arthritis-related research conducted and supported by the National Institute of Allergy and Infectious Diseases (NIAID) focuses on normal and abnormal functions of the immune system, factors involved in inflammation, the possible role of infectious agents, and the influence of genetics.

The immune system is a complex network of organs and specialized cells that mobilize to fight infection. It produces two major classes of cells--B cells, which secrete antibodies, and T cells, which help regulate antibody production. Sometimes the immune response turns against the body's normal tissues and results in what are called autoimmune diseases.

Lupus is a serious and complex autoimmune disease that is characterized in part by enhanced B cell activity and an excess of antibody. Intramural scientist and NIAID director Dr. Anthony Fauci and colleagues have purified and characterized a specific B cell growth factor that may be important in B cell activation. In addition they found that interleukin-2, a T cell growth factor, also enhances B cell proliferation and antibody production. These studies will help clarify exactly how B cell activation occurs and how it differs in normal and disease states.

NIAID scientist Dr. Michael Frank and colleagues have developed a test that may provide further clues about the causes of a number of autoimmune diseases, including lupus, Guillain-Barre syndrome, and multiple sclerosis. The test detects the activation of a group of proteins, called complement, in the spinal fluid of patients with central nervous system symptoms related to these diseases. These proteins, which normally fight bacteria, damage normal tissues in these patients. This discovery may provide a diagnostic test to distinguish brain diseases due to autoimmunity from brain diseases due to other causes.

NIAID intramural scientists under the direction of Dr. Thomas Chused are studying inbred mice that spontaneously develop an autoimmune disorder closely resembling SLE. They have found that, in the New Zealand Black mouse, certain T cells (which suppress the production of antibodies by B cells) enlarge in size just before the disease develops. Enlargement of these cells correlates with their impaired ability to suppress inappropriate autoimmune responses, and the immune system begins to attack normal body tissue.

Some B-cells in New Zealand Black mice are also abnormal, spontaneously producing antibodies when no disease organism is present. Dr. Chused and colleagues have identified a combination of several abnormal genes that cause these defects in the T- and B-cells and lead to autoimmune disease. They have also isolated a previously unknown protein in the affected cells.

Much human autoimmune disease is probably caused by the interaction of several genes. Identification of the genes that cause these abnormal functions of T and B lymphocytes in humans and the development of methods to detect them in patients will lead to improved diagnosis and treatment of human autoimmune disorders.

The National Institute of General Medical Sciences

The National Institute of General Medical Sciences (NIGMS) supports basic research and research training that provide the foundation for a better understanding of fundamental life processes. This research supplies new knowledge, theories, and concepts for a host of diseases, including arthritis.

Diseases such as rheumatoid arthritis, lupus erythematosus, and related disorders are characterized by widespread alterations, including inflammation, of connective tissue. Because collagen is the major protein of connective tissue, cartilage, and bone, studies aimed at understanding the properties of this protein will help scientists learn more about arthritis and related diseases.

Dr. Frederick Silver, an NIGMS grantee at Rutgers Medical School, is studying the mechanisms of collagen fibril formation in test-tube systems and in animal tissues. Collagen fibrils, long cable-like structures which are often grouped in larger bundles, are the most common type of connective tissue fibers. They compose the main mass of such structures as tendons, ligaments, and the intercellular substance of bone and cartilage.

Dr. Silver is using light-scattering techniques to help determine the structure of the collagen molecules, and electron microscopy of various tissues to visualize the relationship between these molecules (while they are in the process of assembling into fibrils) and cell surfaces. He has found evidence of a difference in the mechanisms by which different tissues form collagen fibers. If this proves to be true, it may be helpful in sorting out how the various collagen diseases develop.

Another NIGMS grantee, Dr. Joan Steitz, and her coworkers at Yale University in New Haven, Connecticut, are using sera from patients with autoimmune disorders, particularly lupus, to characterize and determine the structure and function of molecules called small ribonucleic acid protein particles (RNP's). Several types of antibodies react with RNP's in test tube systems.

Dr. Steitz is using these antibodies to help determine the structure of the RNP's. Antibodies that bind with one RNP have been found to inhibit splicing of mRNA (messenger RNA--the molecule that transmits genetic information from the cell nucleus to the cytoplasm, where it directs protein synthesis) in cells. Splicing of the mRNA molecule is an essential step in the process by which the genetic message is transcribed--in turn a step toward translation of the message into protein. This finding is the first direct evidence of the role of RNP's in splicing reactions.

Although Dr. Steitz is using antibodies in the sera of lupus patients to learn more about how basic cellular processes are carried out, knowledge gained from these studies will eventually contribute to our understanding of many diseases, especially autoimmune disorders.

National Institute of Child Health and Human Development

NICHD supports and conducts research on collagen and bone disorders as well as disorders of the immune system.

Studies by intramural scientists Dr. Michael Zasloff and Joan Marini focus on fibrodysplasia ossificans progressiva (FOP). FOP is a rare congenital disease that causes muscle pain and swelling as muscle tissue is gradually replaced by bone. The researchers have found that Tc99 bone scans and CT (computed tomography) scans can delineate the progress of ossification. In addition, CT scans have actually shown new bone developing within the fascia (membrane that separates and envelops muscle) indicating that FOP develops ther rather than within muscle itself.

Looking for chemical changes associated with the disease, Dr. Zasloff and colleagues verified earlier reports that certain prostanins (a family of hormone-like substances that, among other actions, modulate inflammation and immune responses) are associated with FOP. This past year plasma levels of the prostandin PGE_2 were measured in 25 patients, all of whom had markedly high levels of this compound. These patients were also found to have the highest levels ever measured in humans of bone morphogenic protein. It can induce bone formation in man and other vertebrates. These findings have broad implications for our understanding of FOP and of normal bone formation in man.

The researchers are continuing a study to determine the most effective treatment for FOP. A synthetic retinoid, or vitamin A derivative has been found to reduce the appearance of new ossification centers.

Dr. Zasloff and colleagues have also begun new studies of collagen molecular biology and its relation to human bone disease. The focus of research is osteogenesis imperfecta (OI), an inherited condition. Tissue and blood samples of OI patients are being collected and analyzed to obtain information on the hereditary material DNA and RNA. The researchers are working to pinpoint the molecular basis of this disease as well as the normal mechanisms involved in bone development and growth. Earlier research by this group pointed to the polypeptides (precursors of protein) within collagen itself as the source of the defect. Their latest results indicate that a chemical difference in polypeptides does in fact occur in OI victims. Their findings may contribute to the development of a treatment for OI as well as for other human diseases affecting connective tissue.

The development of arthritis is an early symptom of lupus erythematosus. Dr. Sara Walker at the University of Missouri at Columbia, under contract to NICHD, is investigating the effects of various estrogens and progestins on a mouse model (mice) for lupus. She is analyzing death and morbidity rates for treated and untreated mice to ascertain whether various kinds of treatment give survival advantages. This study will offer insight into the best choice of steroids for women suffering from lupus.

National Institute of Environmental Health Sciences

Lead poisoning can produce diverse symptoms including renal toxicity and gouty arthritis (saturnine gout). At the University of Tennessee at Knoxville, Dr. Walter R. Frakas, a National Institute of Environmental Health Sciences (NIEHS) grantee, is examining how lead affects enzymes responsible for purine metabolism. Because purine changes are found in patients suffering from gouty arthritis, this work may help identify how this disease originates. Recently Dr. Frakas has shown that the activity of guanase, a purine metabolism enzyme, is inhibited by low lead ion levels. The role of guanase is to convert guanine to xanthine. Since guanine is very insoluble, lead poisoning may cause an accumulation of guanine precepitates. Using a pig model, lead poisoning was found to induce a fivefold increase in guanine in the extracellular fluid, and crystalline concretions identified as guanine were observed in the region of the femoral head. This study has been extended to primates since purine metabolism in primates and humans is somewhat different than in lower mammals. The investigator found that marmosets that exhibited lead poisoning also had elevated guanine levels in the urine. Thus, these data also implicate altered purine metabolism in the etiology and saturnine gout.

National Institute on Aging

The National Institute on Aging (NIA) supports research on biomedical, social, and behavioral conditions that affect the aging process. Certain types of arthritis are prevalent in older persons. Osteoarthritis (OA)--a degenerative joint disease--occurs in relatively few individuals under age 20 but about half of thepopulation over 60 experiences symptoms.

The cause of OA is not known, although research conducted over the years has produced basic knowledge that clarifies a number of mechanisms underlying the disease. For example, cartilage in persons with severe symptoms of OA has been recognized as being different from cartilage in persons without symptoms.

Dr. William Horton, an NIA grantee at the University of Texas in Houston, is studying the repair process of OA by examining cartilage from patients with various chondrodystrophies. These are a group of rare, inherited cartilage disorders characterized by dwarfism and the tendency to develop OA. Dr. Horton has found that many of the chondrodystrophy cells responsible for repairing osteoarthritic cartilage closely resemble normal cartilage cells. Thus, these osteoarthritic cells produce, at one stage of development, altered cartilage that may be unusually susceptible to degeneration. Dr. Horton's studies should provide insight into abnormal changes in cartilage cells and, possibly, new approaches to therapy. Dr. Horton is currently trying to identify factors that affect the development of OA cartilage cells and to identify how the altered tissue differs from that found in normal joint cartilage.

Division of Research Resources

When administered regularly, low doses of the anticancer drug methotrexate appear to relieve many of the painful and crippling symptoms of rheumatoid arthritis.

A study on methotrexate done at the New England Medical Center General Clinical Research Center (GCRC) in Boston, Massachusetts. The New England Medical Center GCRC is one of 78 such facilities supported by the NIH Division of Research Resources, 48 of which are conducting research on arthritis. Results of the study indicate that, in the absence of alcohol consumption, low doses of methotrexate taken on a weekly basis rarely cause clinically significant liver damage, although high doses of the drug are associated with liver damage when administered to cancer patients.

Liver biopsies were performed on 30 patients with a range of noncancerous diseases before they were given the methotrexate. When pretreatment liver biopsies were compared to those performed on the same patients after 1, 2, and sometimes 3 or 4 years of continued methotrexate treatment, 26 patients showed no liver damage.

The results suggest that methotrexate is only minimally toxic to the liver. Its effectiveness in the treatment of patients with certain forms of arthritis and psoriasis, may thus outweigh the risks associated with its use. Because routine blood tests are not adequate to detect liver damage, the GCRC researchers recommend that patients taking methotrexate on a regular basis undergo liver biopsies at 1- or 2-year intervals. Consumption of alcohol, which may increase the risk of liver damage associated with methotrexate use, should be discouraged in patients taking the drug.

Outlook

Building on resources and knowledge that exist today, researchers are increasingly confident that they can discover the causes of arthritis and related musculoskeletal diseases. The National Institutes of Health and private voluntary organizations have developed a strong and enduring partnership committed to arthritis and musculoskeletal diseases research. This concerted national effort will ensure continued progress toward more effective methods of treating, and ultimately, preventing these diseases and will significantly improve the health of the American public.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

ARTHRITIS

Osteoarthritis and disc degeneration of the spine are major causes of disability in terms of limitation of activity and mobility among many people. Information on the prevalence of arthritis of the knee, hip, and sacroiliac joint has been published from the first National Health and Nutrition Examination Survey. Findings indicate that over 600,000 persons between the ages of 65 and 74 years have moderate to severe osteoarthritis of the knees. About 80 percent of those persons are women.

During 1980 the National Health Interview Survey collected data on musculosketetal conditions in the civilian, noninstitutionalized population of the United States. The estimated number of conditions of known arthritis was 27,772,740 or 127.4 conditions per 1,000 persons. Of these conditions, 20.7 percent caused limitation of activity, 10.8 percent caused one or more bed days in the past year, and 62.1 percent resulted in one or more physician visits in the past year. In 1983, the estimated number of known arthritis conditions was 30,115,000 or 131.3 per 1,000 persons per year.

According to the 1984 National Hospital Discharge Survey, an estimated 464,000 patients were hospitalized in short-stay hospitals in the United States with a first-listed diagnosis of arthritis. Their average length of stay was about 8.2 days. Almost 62 percent of these patients were women and 70 percent of the patients were 45 years and older. About 45 percent of the 464,000 patients had a specific diagnosis of osteoarthritis and allied conditions. There were an additional 1.3 million diagnoses of arthritis that were not first-listed. Although some of these were additional diagnoses for the patients with a first-listed arthritis diagnosis, the majority of these 1.3 million diagnoses were secondary to other diagnoses.

In addition to the figures above, patients with a first-listed diagnosis of spinal arthritis (ankylosing spondylitis and spondylosis and allied disorders) totaled 135,000 discharges in 1984. There were an additional 302,000 secondary diagnoses of spinal arthritis in 1984.

CYSTIC FIBROSIS
Obligations

	1983 Actual	1984 Actual	1985 Actual	1986 Appropriation	1986 Available After Sequestering	1986 Revised Estimate	1987 Estimate
Public Health Service:							
National Institutes of Health:							
National Institute of Diabetes and Digestive and Kidney Diseases....	3,989,000	4,600,000	7,352,000	7,740,000	7,410,000	7,300.000	7,150,000
National Heart, Lung and Blood Institute..........	2,657,000	2,257,000	3,950,000	4,225,000	4,040,000	4,000,000	3,860,000
National Institute of Dental Research...........	1,599,000	2,304,000	4,630,000	5,056,000	4,839,000	4,839,000	4,625,000
National Institute of Allergy and Infectious Diseases...........	2,140,000	2,720,000	4,629,000	4,641,000	4,440,000	4,429,000	4,114,000
National Institute of General Medical Sciences...	50,000	50,000	50,000	50,000	50,000	50,000	50,000
National Institute of Arthritis and Musculoskeletal and Skin Diseases..	$184,000	$212,000	$339,000	$360,000	$345,000	$340,000	$335,000
Division of Research Resources.........	703,000	593,000	0	0	0	0	0
Total, NIH......	11,322,000	12,736,000	20,950,000	22,072,000	21,124,000	20,958,000	20,134,000

NATIONAL INSTITUTES OF HEALTH

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

CYSTIC FIBROSIS

Cystic fibrosis (CF) is the most common lethal genetic disease in Caucasians. Approximately 1 in 2,000 newborns have the disease, which causes a combination of digestive and lung problems. Without intensive treatment, CF can be fatal within a few years. However, with improved diagnosis and more sophisticated treatment available today, many children with CF now live into their twenties and beyond.

CF clearly remains a serious problem and a difficult scientific challenge. While treatment has improved, the disease remains incurable. Research over the years has provided a very thorough description of the features of the disease and the major and minute tissue abnormalities that might serve as clues to the fundamental inherited CF defect. Only recently, however, have scientists found an abnormality that can be demonstrated in a variety of tissues affected by CF. The greatest hope now lies in the use of genetic and molecular biological techniques to pinpoint the biochemical defect that underlies the symptoms of CF.

The Disease

The term cystic fibrosis refers to changes in the pancreas that were noticed by physicians before the disorder was fully described. These early observers noticed cysts and fibrous scarring in the pancreas, a gland just below the stomach. The reason for this scarring is that in CF, the pancreas' secretions into the digestive tract are thicker than usual and can damage the gland by blocking drainage. The pancreas is an exocrine gland--its digestive enzymes are secreted into ducts through which they pass into the digestive tract. (The pancreas also produces endocrine hormones, like insulin, which are secreted into the bloodstream.) CF characteristically affects the secretions of all the body's exocrine glands--the sweat and salivary glands and those that secrete mucus, such as those lining the airways in the lungs and trachea. Mucous secretions are thickened and copious. The thickening of pancreatic secretions results in digestive difficulties in children with CF. Even with an ample diet, these children can be malnourished.

While the lungs of a newborn with CF are normal, over the years the accumulation of mucus makes it difficult for the child to clear his or her lungs of mucus and foreign matter. Coughing becomes chronic, and children with CF are particularly susceptible to bacterial infections of the lung.

The sweat of children with CF is saltier than normal. This feature forms the basis of the current diagnostic test for CF. The sweat test measures salt in sweat and provides a very accurate diagnostic tool.

Treatment for CF at this time is aimed at the secondary effects of the disease. Pancreatic insufficiency is treated with enzyme supplements. Lung disease is treated with a combination of chest physical therapy to loosen lung mucus and antibiotics to control bacterial infections.

There are an estimated 1,000 to 2,000 new cases of CF each year in this country and perhaps 33,000 people with the disease. Five percent of the population, or about 12 million Americans, are symptomless carriers of the disease. If two carriers marry, each of their children has a one in four chance of having CF and a one in two chance of being a carrier.

CF is a costly disease to treat. Hospitalization contributes to the yearly cost of treatment, estimated at about $10,000. Young adults with CF are still vulnerable to the life-threatening lung disease associated with CF. This fact can make planning for the future--from a personal and a professional point of view--difficult. In addition, fertility can be compromised in young men with CF, and pregnancy can threaten the health of young women with the disease.

Research

Research over the years on CF has had two aims: first, improving treatment of the lung disease and digestive effects, and second, identification of the underlying cause. As mentioned previously, early diagnosis and the use of physical therapy and antibiotics have allowed many children to live into their twenties. There may, however, be a limit to how much more increase in lifespan and quality of life is possible through treatment of the secondary effects of this disease. The key to curing CF lies in the identification of the disease's underlying cause for which, in the past, there have been very few helpful clues.

Within recent years, the development of new research techniques and the resulting availability of additional tools with which to explore CF have brought a refocusing of scientific attention on this puzzling disease. In addition, scientists with specialty training in diverse scientific areas are bringing their expertise to CF. The clear pattern of inheritance in CF makes this a disease for which new genetic techniques can be used to pinpoint the familially transmitted defect.

Tissue Abnormalities in CF

Much current research on CF is based on an earlier advance that was a product of research on the excessive saltiness in the sweat of CF patients. Dr. Paul Quinton, a grantee of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK), at the University of California, Riverside, reported a defect in permeability to the chloride ion in isolated sweat ducts. Chloride, part of the sodium chloride compound that is table salt, is important in fluid balance in the body. The defect in permeability to chloride has since been confirmed in cells that line the airways, the nasal passages, and the trachea. Scientists hope that identification of the cause of this defective permeability may provide the avenue for determining at a cellular level how the disease does its damage.

In continuing work, Dr. Quinton has tested whether sweat from CF patients can affect the secretory properties of normal sweat glands. Many scientists have postulated and sought the existence of a CF "factor" in the exocrine secretions of CF patients that would cause the alterations in tissue function characteristic of the disease. Dr. Quinton reported no such measurable effect of sweat on normal gland function, narrowing the range of options by which a biochemical defect might act to cause CF.

Scientists are also looking at the neurologic control of sweat glands. Research conducted by Dr. Kenzo Sato at the University of Iowa, Iowa City, has demonstrated that in CF, sweat glands do not respond normally to nervous system stimulation that is usually important in controlling the function of the glands. Responsiveness of other organ systems to this kind of stimulation, or sympathetic nervous system control, has also been observed to be abnormal in people with CF, another clue that there is a generalized defect in sympathetic nervous system responsiveness in CF.

If so, the next step would be to determine how such a defect would originate. The sympathetic nervous system characteristically acts through a "second messenger" or intermediary molecule, cyclic AMP. Dr. Sato's research has shown that isolated sweat glands from CF patients accumulate a normal amount of cyclic AMP in response to sympathetic nervous system stimulation. This finding suggests that the abnormality in the neurologic response of the sweat gland may not result from a defect in accumulation of cyclic AMP, but in a later step in the chain of biochemical events leading to sweat secretion.

Calcium is another intracellular messenger that can influence a cell's metabolic responses. Scientists are conducting research to characterize the role of calcium in metabolic control and to determine whether calcium turnover is abnormal in CF. For example, Dr. Dorr Dearborn and colleagues at the Cystic Fibrosis Center at Case Western Reserve University, Cleveland, have looked at calcium distribution in cells from CF patients. They found that total intracellular calcium is about 25 percent higher in CF cells than in cells from individuals without CF. Half of this calcium is contained in mitochondria, cell organelles that have an important function in energy metabolism. Continuing research will be aimed at identifying what the defect in calcium metabolism is and how it may contribute to an abnormality in metabolic control in these tissues.

The defects described above reside in the cells that line the surfaces of exocrine glands and ducts. In order to study the properties and defects of these so-called epithelial cells, cell culture techniques have to be expanded to provide a constant supply of healthy cells for experimentation. NIADDK sponsored a workshop in July 1985, bringing together experts in research on CF epithelial tissues and tissue cell culturing to promote collaboration in the development of these techniques. Among the scientists who discussed the tissue culture techniques developed for tissues affected by CF were NIADDK grantees Dr. Donald Sens, of the Medical University of South Carolina, Charleston, who is studying sweat gland duct cells and Dr. Carol Liedtke, Case Western Reserve CF Center, who is studying rabbit tracheal epithelial cells.

The groundwork for current cell culture techniques has been laid by years of basic research. The technologies for isolating, culturing, and manipulating cells have advanced tremendously and have made possible the studies of ion transport and neurologic response described above.

Genetics

Another approach to identifying the CF defect, and one that is now receiving great emphasis, is to search for the defective gene. The protein product of the gene can then be determined using the genetic code, and the effects of this protein on cell function can be studied. This research has gained momentum within the last year. NIADDK has actively solicited research applications for grants to study the genetics of CF, and has funded several new studies in the past year. The principal investigators on these projects bring their expertise in cell genetics to a field that needs and lends itself to this kind of investigation.

These opportunities in genetics are only now becoming available because of recent advances in techniques that allow scientists to screen for genetic anomalies and determine whether they are linked to CF. CF provides a good opportunity for this kind of investigation because the pattern of its inheritance is clear. It is inherited as a single recessive trait, that is, a child must inherit the gene from both parents to have the disease.

An NIADDK-supported investigator, Dr. Lap-Chee Tsui, at the Hospital for Sick Children in Toronto, has just discovered a marker that appears to be inherited along with the CF gene with a high degree of frequency. At the same time, another NIADDK-supported investigator, Dr. Katherine Klinger, at Integrated Genetics, Rochester, New York, has found evidence that another marker was transmitted with the CF gene. These preliminary reports suggest that research in this area has the potential for exciting new discoveries.

In addition to supporting research of this type, NIADDK has initiated a collaborative program with the Department of Energy (DOE) under which its laboratories at Los Alamos, New Mexico, will be making specially prepared filter paper sets impregnated with pieces of DNA from each human chromosome. This central resource will spare independent investigators from having to acquire the equipment and personnel to prepare such material themselves, saving duplication of effort and funds. The filter paper can be used repeatedly to determine on which chromosome a given gene marker is located. This resource should be useful for research on CF and a host of other genetic disorders.

NIADDK is also funding another resource that will facilitate genetic research on CF. The Human Genetic Mutant Cell Repository in Camden, New Jersey, is collecting blood cells from families with CF to provide DNA for genetic studies. This program is described more fully later in this report by the National Institute of General Medical Sciences (NIGMS).

Genetic markers for diseases can be used for prenatal screening and postnatal diagnosis. Ultimately, however, the search for genetic markers is an avenue to finding the CF gene and developing a treatment. For example, the CF mutation may result in the absence of an essential protein or the presence of a harmful one. Treatment in the first case might be to replace the missing protein, and in the second case to suppress the abnormal gene with drug therapy. The development of therapy directed at the gene depends on continued technological advances. In the future, such therapy might seek to clone and introduce normal genes into CF-affected tissues.

NIADDK Intramural CF Program

A recent reorienting of NIADDK's intramural research on CF has led to an interdisciplinary program of basic research on many aspects of the disease: ion transport; mucus and exocrine secretory problems; infections and immunology; genetics; and the structure and metabolism of glycoproteins, compounds that are important in the structure of mucus and immune substances. Under NIADDK's new CF Fellowship Program, physicians with an interest in CF are recruited for a 1- to 2-year fellowship in a specific area of basic research. The Cystic Fibrosis

Foundation is aiding this program with grants that supplement the salary of each research fellow, making it possible to attract well-qualified individuals. The scientists collaborate with NIADDK scientists on basic research related to CF. This program started in the spring of 1984, and the research is well under way.

Dr. Richard Ornberg is an NIADDK intramural scientist who is doing research related to CF. He is using an analytical electron microscope recently developed by National Institutes of Health scientists in the Division of Computer Research and Technology and the Division of Research Resources to gather information on how cells secrete substances. With the analytical microscope, one of the most sophisticated in the world, Dr. Ornberg can visualize changes in distribution of chemical elements within a secretory cell's storage granule as it resides in the cell under living conditions. This information promises to help contribute to an understanding of exocrine secretory processes and the defects in secretion that occur in CF.

National Heart, Lung, and Blood Institute

As discussed in the previous section, the fundamental flaw in CF may involve the movement of certain ions--notably chloride--across cell membranes in various tissues. Chloride ions move into or out of cells through designated channels in the cell membrane, always in the direction of favorable electrochemical gradients much as water in a stream follows the streambed and always flows downhill. According to some investigators, in CF patients there appears to be some malfunction or structural defect in the chloride channel that impedes the movement of this ion.

Dr. Richard Boucher and co-workers, National Heart, Lung, and Blood Institute (NHLBI) grantees at the University of North Carolina in Chapel Hill, studied ion movement in epithelial cells obtained from nasal polyps that had been removed from CF patients or from hay-fever sufferers. Under the conditions of the experiment, chloride ion movement across the membranes of cells from the CF patients was only half that seen in cells from the control individuals. Other evidence strongly indicated that the impedence of chloride movement in the CF cells was not due to any local or circulating mediator substance, but rather was intrinsic to the cells themselves. Similar impedence of chloride movement has been found by other investigators in tracheal cells and in sweat ducts from CF victims. In all these instances the cells exhibiting the chloride transport abnormality were from tissues known to be adversely affected by CF.

Of the disease-causing agents that take up residence in the lungs of CF patients--and which are often difficult and sometimes impossible to dislodge even with vigorous therapy--the bacterium Pseudomonas aeruginosa can be especially troublesome. Dr. Kenneth B. Alder and co-workers, NHLBI-supported investigators at the University of Vermont in Burlington, report that apart from the toxin this organism produces, it also elaborates an extracellular substance that, when added to a medium containing guinea pig or human tracheal tissues, stimulates them to produce and release increased quantities of mucin, the major component of mucus. This occurs in the absence of any detectable structural or toxic changes in the secretory cells of these tissues or any proliferation of their mucosa. The investigators think that it may also happen in the lungs of CF patients with P. aeruginosa infections and may well be an important factor in the excessive mucus that clogs their airways and fosters bacterial growth and replication. The investigators wonder whether this otherwise uncommon respiratory organism might not be helping to create an environment that enhances its own survival in CF patients.

With more CF patients surviving through their twenties and into their thirties, cor pulmonale--heart disease resulting from lung disease--has become an increasingly prevalent complication of CF. Oxygen deficiency resulting from CF-associated lung problems may cause blood pressure in the pulmonary circulation to increase. In turn, this increases the circulatory burden of the heart's right ventricle, which may cause it to enlarge and, ultimately, to fail. Presently, the treatment of choice for cor pulmonale in CF is oxygen therapy, which selectively dilates pulmonary blood vessels, reduces pulmonary pressure, and improves oxygen delivery to organs and tissues; but the search continues for better therapeutic regimens for these patients.

Blood vessel dilators have been used with some success to treat pulmonary hypertension and cor pulmonale in patients with chronic obstructive lung disease. Therefore, Dr. Robert L. Geggel and co-workers, NHLBI grantees at Children's Hospital Medical Center in Boston and Harvard Medical School in Cambridge, Massachusetts, tested several of these dilators (phentolamine, nifedipine, and hydralazine) in patients with cor pulmonale due to CF, comparing the results obtained with the drugs to those obtained with oxygen therapy. None of the drugs was nearly as effective as oxygen therapy. Though hydralazine did improve heart performance and oxygen delivery somewhat, none had any significant effect on the pulmonary hypertension in these patients. The investigators conclude that oxygen therapy remains the treatment of choice for cor pulmonale secondary to CF, and that blood vessel dilators cannot be recommended unless subsequent study shows that the modest effects of hydralazine on heart performance and oxygen delivery favorably affect the prognosis in such patients.

National Institute of Dental Research

Among the effects of CF are and abnormal changes in salivary glands. Saliva plays a key role in protecting the mouth against infection. It also lubricates the oral tissues, helping to make food easier to swallow.

Saliva is normally a clear, free-flowing liquid. The saliva of CF patients, however, may be thick, sticky, and characterized by extremely viscous secretions. This abnormal saliva can block the salivary ducts, causing the glands to enlarge and become vulnerable to infection. It may also contribute to functional problems, such as difficulty of speech and swallowing, and may increase the risks of dental and oral soft-tissue disease.

The National Institute of Dental Research (NIDR) conducts and supports extensive study of the mechanisms that normally control exocrine gland secretion in order to determine what goes awry in disorders such as CF. NIDR intramural investigator Dr. Bruce Baum has used animal salivary glands to study the mechanisms controlling saliva formation. By focusing on how the involuntary nervous system regulates secretions under normal conditions, abnormal conditions, and during aging, Dr. Baum and his coworkers hope to gain a better understanding of how salivary glands fail in patients with CF.

Saliva contains a broad spectrum of proteins that are known to play a pivotal role in maintaining the health of hard and soft oral tissues. The parotid gland--a major salivary gland--secretes many antibacterial proteins which carry sugar residues and are called N-linked glycoproteins. Dr. Eleni Kousvelari heads a team of investigators at NIDR who are studying the mechanisms involved in the processing, synthesis, and secretion of N-linked glycoproteins. They have discovered that alterations in chemical signals from nerves can affect how these glycoproteins are made and how they function.

Knowledge of the intracellular events associated with the secretory process may provide valuable insight into diseases such as CF. Dr. Eileen Watson of the University of Washington School of Dentistry in Seattle is conducting an NIDR-supported study of the mechanisms by which calcium ions regulate the secretory process. She is investigating the calcium-binding protein calmodulin, sodium ions, and cyclic AMP, as well as the relationship between calcium and these chemical messengers.

In another extramural project, Dr. James W. Putney, Jr. of the Medical College of Virginia in Richmond is studying the pharmacology of salivary secretion. In laboratory studies, Dr. Putney is defining the pattern and sequence of signals transmitted from the cell surface and within the cell that are necessary to trigger the production and secretion of saliva. Studies of this kind, which define the cellular and molecular mechanisms of salivary secretion, improve understanding of the role of salivary secretion in dental health and define basic exocrine functions as they relate to CF.

National Institute of Allergy and Infectious Diseases

Patients with CF are particularly susceptible to life-threatening respiratory infections. Through its extensive research programs, the National Institute of Allergy and Infectious Diseases (NIAID) supports studies aimed at preventing and controlling some of the major respiratory problems that affect CF patients.

Pulmonary symptoms of CF include excessive mucus secretion, recurrent infection and inflammation, and irritable air passages. It is, therefore, of vital importance to define factors that may result in these symptoms. NIAID grantee Dr. Robert E. Lemanske, Jr., at the University of Wisconsin-Madison has observed that similar, albeit less severe symptoms, occur in patients with allergic asthma. Like these asthmatics, CF patients have an increased incidence of positive skin tests for the presence of allergies. These important findings suggest an association between allergy and the pulmonary symptoms seen in patients with CF and those with allergic asthma.

Allergic reactions produce both immediate responses, which occur in minutes, as well as late responses, which occur over a period of hours or days. Late responses may result in pulmonary inflammation and mucus secretion by mechanisms that are, as yet, undetermined. Observations by Dr. Lemanske and his colleagues indicate that these reactions may contribute to the pulmonary symptoms observed in CF patients and allergic asthmatics.

In studies with rats, Dr. Lemanske and his colleagues have produced pulmonary allergic reactions and have demonstrated that these responses cause inflammation of the air passages. Further, they have isolated mast cells, which are cells in the body responsible for allergic reactions, and demonstrated that these cells contain factors that induce inflammatory changes within the lungs of these animals. These experiments indicate that allergic reactions in the lungs can lead to inflammation.

The investigators are also measuring pulmonary function in these experimental animal models to determine if the inflammatory response in any way compromises airway function. Results of these studies are providing vital insight into how allergic reactions may participate in chronic inflammatory diseases of the lungs. With this knowledge, scientists are optimistic that better treatments can be developed, not only for patients with CF, but also for patients with allergic asthma.

Most lung infections in CF patients are caused by _Pseudomonas aeruginosa_. Once a _Pseudomonas_ infection is established, it is virtually impossible to eliminate with antibiotics; therefore, an effective vaccine could prevent the tragic suffering and loss of lives caused by this virulent organism. One of the major goals of NIAID's research on CF is the development of a non toxic _Pseudomonas_ vaccine to be given to CF patients before their first infection by the bacterium.

An important study on the development of such a vaccine is being conducted by NIAID grantee Dr. James E. Pennington at the Brigham and Women's Hospital in Boston. He and his colleagues have demonstrated that immunization of guinea pigs with a *Pseudomonas* vaccine significantly protects against experimentally induced chronic *Pseudomonas* pneumonia. This lung protection was manifested by reduced numbers of the bacterium in the lungs of vaccinated guinea pigs and amelioration of the lung infection.

Additionally, the researchers are evaluating a variety of immunizing regimens to determine the most feasible, yet protective, method. Adverse and/or beneficial effects of giving steroids (agents that reduce inflammation) during chronic *Pseudomonas* lung infections are being assessed, and the interactions of LPS immunization and steroids in experimental animals are being studied.

The scientists are optimistic that the vital information furnished by these studies will provide the information necessary for planning and developing clinical trials of a *Pseudomonas* vaccine in CF patients.

The National Institute of General Medical Sciences

NIGMS supports research and research training in basic fields that provide the foundation for a better understanding of fundamental life processes. One of NIGMS' major programs supports basic research on genetics. This research supplies new knowledge, theories, and concepts that may lead to improved diagnostic techniques and treatments for many diseases, including CF.

While the hereditary pattern for the transmission of CF is well known, no genetic defect has yet been found that can account for the disease's symptoms. Studies to identify such a defect are facilitated by the Human Genetic Mutant Cell Repository, supported by a contract from NIGMS to the Institute for Medical Research in Camden, New Jersey. Recently, the repository has had as one of its highest priorities the establishment of a CF cell collection to aid in identifying the genetic basis of this disease. To this end, the repository has now acquired cell lines from six families, each of which contains at least three affected siblings as well as normal siblings, and the parents. This brings to 115 the number of cell lines in the repository from CF patients and unaffected family members. These cell lines, along with detailed background material, are made available to investigators at a modest charge and are among the items requested most frequently from the repository. Using these cell lines, a number of laboratories are currently attempting to correlate the expression of CF with inherited variations in certain genetic sequences, known as restriction fragment length polymorphisms (RFLPs). Finding such a correlation, or linkage, to an RFLP could permit accurate prenatal diagnosis of the defect, isolation and characterization of the gene for CF and possible therapy.

Outlook

While research has not yet provided a cure for CF, it has provided the tools that are enabling scientists to close in on CF. Momentum has built in the last year in research in which scientists are using state-of-the-art scientific techniques to explore CF. CF's clear genetic mode of inheritance now becomes a candidate for analysis, as it is the type of disease for which genetic techniques can be the most fruitful. Through the trans-NIH CF Coordinating Committee, for which NIADDK has lead responsibility, the Institutes with an interest in CF have worked cooperatively to develop programs in support of new research initiatives. The goal of the committee and of NIH research is to continue to identify and stimulate new opportunities for studying this disease and draw on expertise developed in other fields to conquer this one. The outlook is more promising than ever.

OFFICE OF HUMAN DEVELOPMENT SERVICES

REPORT ON DAY CARE

OFFICE OF HUMAN DEVELOPMENT SERVICES

Federal Funds Expended for Day Care

(amounts in thousands of dollars)

	1985 ACTUAL	1986 ENACTED	1986 POST-GRH	1986 REVISED BUDGET	1987 ESTIMATE
SOCIAL SERVICES BLOCK GRANT					
Day Care Services....	1/	1/	1/	1/	1/
HUMAN DEVELOPMENT SERVICES					
Head Start..	1,075,059	1,087,059	1,040,315	1,040,098	1,075,059
Child Welfare Services....	2/	2/	2/	2/	2/
Subtotal..	1,075,059	1,087,059	1,040,315	1,040,098	1,075,059
WORK INCENTIVE PROGRAM					
Child Care Services....	36,570	32,017	30,636	23,718	-0-
TOTAL DAY CARE......	1,111,629	1,119,076	1,070,951	1,063,816	1,075,059

1/ No reports of actual usage of these funds are required from the States so that no estimates are available of how much of the funds are used for Day Care.

2/ Funds from the Child Welfare Services Program provide a match for State monies for a variety of social services to children and their families including day care services. No reports of actual usage of these funds are required from the States. Therefore no estimates are available of how much of the funds are used for Day Care.

SOCIAL SERVICES BLOCK GRANT
Day Care

Under Title XX of the Social Security Act, as amended by the Omnibus Budget Reconciliation Act, Public Law 97-35, Block Grants are made to States to provide an array of services, one of which is day care services to children and adults. The services may be provided in the individual's own home or outside the home, including care in family day care homes, group day care homes, and day care centers.

The day care services furnished should be suited to the age, special handicaps, or other conditions of the individuals, with participation of responsible relatives insofar as possible.

Beginning with fiscal year 1982, this program is administered by the States as a part of the Social Services Block Grant. The 1985, 1986, and 1987 appropriation levels for the Block Grant are $2.725 billion, $2.5839 billion, and $2.7 billion respectively.

	1985 ACTUAL	1986 ENACTED	1986 POST-GRH	1986 REVISED BUDGET	1987 ESTIMATE
SOCIAL SERVICES BLOCK GRANT					
Day Care Services....	NA 1/	NA 1/	NA 1/	NA 1/	NA 1/

1/ No reports of actual usage of these funds are required from the States so that no estimates are available of funds used for Social Services Block Grants Day Care.

HUMAN DEVELOPMENT SERVICES

Administration for Children, Youth, and Families

The Administration for Children, Youth, and Families (ACYF), located within the Office of Human Development Services, serves as an advisor to the Secretary, the Assistant Secretary for Human Development Services, and other Federal agencies on matters pertaining to the care and development of children.

Child Development program efforts aim at improving child care delivery systems and designing programs to improve the quality of life for children and their families throughout the Nation. Major activities are focused on meeting the developmental needs of pre-school-age children from low-income families through the Head Start Program. In addition, the Child Welfare Services program provides funds to match State money for a variety of social services including day care.

Head Start

	1985 ACTUAL	1986 ENACTED	1986 POST-GRH	1986 REVISED BUDGET	1987 ESTIMATE
Head Start (total)	1,075,059,000	1,087,059,000	1,040,315,000	1,040,098,000	1,075,059,000

Head Start is a comprehensive pre-school program which serves children and their families, primarily those who are poor. It encompasses a wide range of developmental activities including education, medical, dental, nutritional, social, and other services with particular emphasis on parent involvement. A variety of training and technical assistance activities are provided to local program staff to enhance the quality and effectiveness of the services offered. Head Start also conducts experimental programs such as the Child and Family Resource Program which provides family-oriented child development services according to the assessed needs of individual children, and Developmental Continuity, a program to facilitate continuity of educational and social gains made in pre-school programs into elementary school.

Head Start assures that 10 percent of the enrollment opportunity in each State is available to handicapped children. This is in accordance with the legislative mandate contained in the authorizing statute. Head Start now provides services to handicapped pre-school children in an integrated setting with the non-handicapped and has established service delivery linkages with State and local agencies concerned with handicapped children.

The Head Start policy states that the appropriate duration of an education or enrichment program for pre-school children is no more than six hours per day. Beyond this period, it is desirable for a child to "return to his own family unless there is no suitable care-giver in the home due to employment, illness, or other reason." Only in such cases may the basic Head Start program be supplemented to provide full day care for the child.

Low income children and families, like other segments of the community, differ greatly in their need for child care and developmental services. Ideally, Head Start programs should be tailored to the special and diverse needs of each individual community and child, with particular emphasis placed on serving those with the greatest need. Thus, size permitting, each Head Start program can provide a balanced program of remedial and developmental services that reflects the full array of needs in the community.

Child Welfare Services

Title IV of the Social Security Act (Child Welfare Services Grant Program) provides funds to match State money for a variety of social services to children and their families including day services. There is no income test for eligibility for these services except as set by individual States.

	1985 ACTUAL	1986 ENACTED	1986 POST-GRH	1986 REVISED BUDGET	1987 ESTIMATE
Child Welfare Services day care.....	NA 1/	NA 1/	NA 1/	NA 1/	NA 1/

1/ No reports of actual day care expenditures are required from the States so that no estimates of funds used for day care are available.

WORK INCENTIVE PROGRAM
WIN Day Care

The Work Incentive program, authorized under Title IV of the Social Security Act, is a State-administered program designed to encourage and assist recipients of Aid to Families with Dependent Children (AFDC) to achieve self-support through a program of training, work experience, employment, child care, and other supportive services. The 1971 Amendments to the Social Security Act authorized child care and other supportive services to be provided to all WIN registrants who need such care and services to enable them to accept work or training. State expenditures are matched by Federal payments at the rate of 90%.

In Fiscal Year 1986, under the Direction of the Office of Family Assistance (OFA-HHS), twenty-six States will operate WIN Demonstration programs to test the effectiveness of a single agency administration. OFA does not collect child care data from their WIN Demonstration program States which will use about 71% of the WIN funds.

Child care services include full-time and part-time care for children of WIN participants. Child care may be provided in their own home, in family day care homes, or in day care centers. Of the child care provided, about two-thirds is full-time and one-third is part-time. Child care for children in their own homes accounted for about 48% of the total, while 33% were estimated to receive care in family day care homes and 19% were estimated to be cared for in day care centers.

	1985 ACTUAL	1986 ENACTED	1986 POST-GRH	1986 REVISED BUDGET	1987 ESTIMATE
Federal funds...	$36,570,000 1/	$32,017,000	$30,636,000	$23,718,000	--
Average Quarterly Number of Children Receiving Day Care....	38,400 2/	32,400	31,000	24,000	--
Number of New Registrants:	1,013,000 3/	700,000	670,000	518,400	--

1/ Based on Report SF-269 expenditures for contracted child care plus one-third of staff costs, plus proportionate share for estimated Demo expenditure.

2/ Based on consolidated Report 5's from HHS, FY1981.

3/ Based on actual data reported in DOL/ETA ESARS report for FY1985, and actual/estimated data from OFA reports. The FY1986 estimate is based on the FY1986 appropriation.

DIABETES AND RELATED RESEARCH
Obligations

	1983 Actual	1984 Actual	1985 Actual	1986 Appropriation	1986 Available After Sequestering	1986 Revised Estimate	1987 Estimate
Public Health Service:							
National Institutes of Health:							
National Institute of Diabetes and Digestive and Kidney Diseases..	$84,500,000	$92,444,000	$103,977,000	$109,500,000	$104,700,000	$103,100,000	$101,100,000
National Cancer Institute........	634,000	650,000	454,000	600,000	620,000	580,000	560,000
National Heart, Lung and Blood Institute........	16,720,000	17,121,000	19,135,000	20,500,000	19,600,000	19,300,000	18,700,000
National Institute of Dental Research.........	1,997,000	2,098,000	4,523,000	4,922,000	4.710,000	4,710,000	4,600,000
National Institute of Neurological and Communicative Disorders and Stroke...........	6,639,000	7,430,000	4,314,000	4,719,000	4,516,000	4,412,000	4,365,000
National Institute of Allergy and Infectious Diseases.........	5,408,000	5,452,000	5,692,000	5,886,000	5,633,000	5,605,000	5,345,000

DIABETES AND RELATED RESEARCH (continued)

Obligations

	1983 Actual	1984 Actual	1985 Actual	1986 Appropriation	1986 Available After Sequestering	1986 Revised Estimate	1987 Estimate
Public Health Service:							
National Institutes of Health:							
National Institute of General Medical Sciences.	943,000	849,000	1,056,000	1,100,000	1,100,000	1,100,000	1,100,000
National Institute of Child Health and Human Development......	8,692,000	10,758,000	11,545,000	11,900,000	11,400,000	11,300,000	11,400,000
National Eye Institute.........	21,054,000	22,696,000	20,850,000	23,200,000	21,600,000	21,500,000	21,300,000
National Institute of Environmental Health Sciences..	132,000	331,000	311,000	315,000	315,000	315,000	320,000
National Institute on Aging.........	2,362,000	1,797,000	2,007,000	2,182,000	2,089,000	2,056,000	2,036,000
Division of Research Resources........	16,190,000	16,356,000	15,107,000	15,462,000	14,797,000	14,797,000	14,105,000
Total, NIH....	165,271,000	177,982,000	188,971,000	200,286,000	191,080,000	188,775,000	184,931,000
Centers for Disease Control..........	5,980,000	5,980,000	7,480,000	7,480,000	7,158,000	2,373,000	2,480,000
Total, PHS........	171,251,000	183,962,000	196,451,000	207,766,000	198,238,000	191,148,000	187,411,000

NATIONAL INSTITUTES OF HEALTH

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

DIABETES MELLITUS

Between 10 and 11 million Americans, about 1 in 20, have diabetes mellitus, often simply called diabetes. This chronic disease interferes with the body's ability to derive energy from glucose, a type of sugar that is an important product of digested food.

When diabetes strikes children, it is in a form that requires daily injections of the hormone insulin. Most people with diabetes have another form of the disease that begins in adulthood and that can escape notice by the person affected for many years.

While the onset of childhood, or insulin-dependent diabetes can be much more dramatic than that of an adult [illegible] noninsulin- dependent diabetes, both afflictions are life-threatening. Both are associated with complications that can develop even while the underlying diabetic condition causing them is being treated. The complications--among them, eye, kidney, heart, and nerve disease--can be serious and, for most diabetic patients, are the disease's greatest threat.

The understanding that diabetes has more than one cause--and that different forms of diabetes result in the same long-term complications--is a product of research conducted in the years following the first great diabetes breakthrough, the discovery of insulin in 1920. Based on this new understanding of diabetes, more recent research has focused on insulin-dependent diabetes (IDDM) and noninsulin-dependent diabetes as conditions that must be approached individually in both research and therapy in different ways.

This research has led to such major developments as new purified forms of insulin, synthetic human insulin made by recombinant DNA techniques, blood glucose monitoring technology, and insulin pumps, all important options for people with IDDM. While these technologies can also be applied in NIDDM, this disorder is now recognized as one that can, in the majority of cases, be treated and often prevented through diet and exercise.

Even with these advances, there is as yet no cure for diabetes, and the complications of this disease remain a threat:

- o People with diabetes are about twice as likely as those without diabetes to have heart disease.

- Strokes occur about 2 to 6 times more frequently in people with diabetes than in those without the disease.

- After 15 years of diabetes, about one-third of persons with IDDM and one-fifth of people with NIDDM have signs of kidney disease. Diabetes accounts for a quarter of all new cases of end-stage renal (kidney) disease.

- Diabetes is the leading cause of blindness in middle-aged Americans.

- Perinatal mortality--death of an infant occurring any time from about the 20th week of pregnancy to several weeks after birth--is 2 to 4 times higher in pregnancies in which the mother is diabetic than in pregnancies uncomplicated by diabetes. Five to 10 percent of infants of women who are diabetic before they become pregnant have congenital malformations at birth.

While the complications of diabetes can be a serious threat to health, research is providing information that can be used to minimize the risk and the disability from these conditions. For example:

- Through research, scientists have determined that careful control of blood glucose levels in a pregnant diabetic mother can reduce the risk of perinatal mortality to that seen in mothers without diabetes. By controlling diabetes before the woman becomes pregnant, it may now be possible to eliminate the increased risk of congenital malformation in infants of diabetic mothers.

- Application of techniques now available for preventing and caring for sores and infections in the legs and feet of people with diabetes could reduce by an estimated 50 percent the number of amputations necessary as a result of diabetes.

- Improved treatments for diabetic eye disease can greatly reduce the incidence of blindness associated with diabetes. Through research on eye complications, scientists have developed drug treatments now being tested for their potential in preventing eye disease and other complications of diabetes.

- Research has laid the groundwork for a major clinical trial now under way to test whether very careful diabetes control can prevent or limit diabetic complications.

Even more hopeful than these advances, however, is the increasing ability of scientists to use new research techniques to probe the mechanisms that underlie normal metabolism and the defects that cause diabetes. This year, scientists were able to clone the gene for the insulin receptor. Insulin-producing cells (islet cells) of the pancreas were extracted and purified using new techniques and transplanted into human patients for the first time. New synthetic techniques were used to produce a chemical facsimile of glucagon, a hormone that, like insulin, regulates glucose metabolism. All these advances were made possible by new technologies developed in the course of basic research. In time, discoveries made possible by these technologies may lead to solutions to diabetes as a public health problem.

The Causes of Diabetes

Insulin is a hormone made by the pancreas, a gland located just below the stomach. Insulin is essential for the normal metabolism of glucose. If there is insufficient insulin, or if insulin for some reason does not act effectively, blood glucose rises. Diabetes treatment is aimed at lowering elevated blood glucose levels.

Insulin-Dependent Diabetes Mellitus and the Immune System

People with insulin-dependent diabetes (IDDM) make no insulin and therefore must have injections of the hormone each day to survive. An increasing amount of evidence supports the theory that the pancreas' ability to secrete insulin is lost in IDDM as a result of the destruction of insulin-secreting cells by the patient's own immune, or disease-fighting, system (a so-called autoimmune process). Among the evidence are findings of altered activity of white blood cells, which normally play important roles in immune responses.

A strain of rats developed at the University of Massachusetts at Worcester has provided an important resource for research on IDDM. These rats have a genetic predisposition to developing a form of IDDM. Last year, Dr. Aldo Rossini and colleagues at the university showed that transfusions of whole blood from healthy rats to diabetes-prone animals could prevent the onset of diabetes. This year, the group showed that certain types of white blood cells transfused from healthy to diabetes-prone rats had the same effect, demonstrating that the white blood cells were responsible for protection from the disease.

In a complementary line of research in human patients, scientists Dr. Richard Spielman, Dr. Franz Matschinksy, and colleagues at the University of Pennsylvania, Philadelphia, compared the production of a substance called interleukin-2 (IL-2) by white blood cells in 26 people with IDDM, 6 people with NIDDM and 40 nondiabetic volunteers. White blood cells release IL-2 when they are sensitized or "aroused" by the presence of a foreign substance.

The researchers found that white blood cells (WBCs) in the IDDM patients produced less IL-2 than WBCs in either of the other two groups. The decreased IL-2 production may impair the defensive response to a viral infection of the insulin-producing islet cells in the pancreas, or may create an imbalance in the immune system that could make the cells vulnerable to harm from autoimmune destruction.

The studies on the diabetes prone rats and on human immunologic responses are providing a clearer picture of how the immune system is involved in IDDM and how the disease might one day be prevented. Both are examples of research conducted at National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK)-supported Diabetes-Endocrinology Research Centers (DERC's). DERC's and Diabetes Research and Training Centers (DRTC's) receive support to establish "core" research facilities, each with specialized research capabilities. Scientists can draw on each core's expertise rather than duplicating equipment and training. The core concept is important in an era of increasing scientific specialization.

Noninsulin-Dependent Diabetes Mellitus and the Insulin Receptor

In the University of Pennsylvania studies just described, the white cell responses of NIDDM patients were the same as in volunteers without diabetes. This finding reflects the fact that NIDDM and IDDM do not have the same underlying cause. While there is probably a defect in the function of insulin-producing cells in NIDDM, the pancreas retains an ability to secrete the hormone in this disease. As a result, scientists are having to look beyond the pancreas for the cause of NIDDM.

The explanation for NIDDM lies at least partially in the tissues on which insulin acts. Cells of the target organs of insulin have surface receptors for the hormone. To act on the cell, insulin must bind with these receptors, and the hormone-receptor binding sets off a series of steps, as yet incompletely understood, which result in the processing of glucose by the cell.

Defects in insulin receptors or in the steps that follow binding of insulin to the receptor are thought to be part of the cause of NIDDM. Such defects would reduce the effectiveness of insulin even when the person affected produced normal amounts of the hormone, a condition called insulin resistance. Insulin resistance is a hallmark of NIDDM and contributes to elevated blood glucose.

A major step forward this year in research on insulin action was the determination of the structure of the insulin receptor and the gene that determines this structure. Two groups of researchers, among them NIADDK grantees at Memorial Sloan-Kettering Cancer Center, New York; the University of California, San Francisco; Mt. Zion Hospital and Medical Center, San Francisco; and Stanford University, Stanford, California, reported making this advance using slightly different techniques. With this information, scientists can test concepts of how the receptor is synthesized, how it is oriented on the cell surface, how it interacts with insulin, and how it acts on intracellular machinery to influence the use of glucose by the cell.

The availability of the insulin receptor presents new opportunities for NIADDK scientists who have been studying it. Two years ago, NIADDK intramural scientists reported that when insulin binds to its receptor, the insulin-receptor unit responds by incorporating phosphate from the cell at a specific site in the insulin receptor. The incorporation of phosphate--or phosphorylation--is known to be a regulatory step, sort of a biochemical "switch," in living systems. These and other researchers subsequently studied this process in people with syndromes of extreme insulin resistance. Some scientists have reported that the phosphorylation step is altered in these conditions.

To further understand the role of phosphorylation in metabolism, scientists have been studying other growth-regulating proteins that, like the insulin receptor, are capable of phosphorylating proteins. One class of these proteins includes the receptor for epidermal growth factor (EGF). Another class consists of the products of oncogenes, or cancer-causing genes found in viruses. Recently, NIADDK intramural scientists Drs. Jesse Roth, Simeon Taylor, and colleagues reported that they had used immunologic techniques to show that the EGF receptor shared much of the structure of the protein product of a viral oncogene. Like the EGF receptor, the viral protein promotes growth and can phosphorylate other proteins. This research showed that these shared functions are apparently reflected in shared structure. However, the viral protein lacks a control sequence present on the EGF receptor. It appears that viruses can take over genes coding for growth-promoting proteins that occur normally in cells. The discovery of these similarities between growth-promoting proteins in viruses and cells was a fascinating surprise. Study of these interrelationships can provide insight on the mechanism of how these substances stimulate growth, and how the processes they control can go awry.

Clinical research on the mechanisms of insulin action and resistance is under way at NIADDK's Phoenix Clinical Research

Center in Arizona. The Pima Indians of this area have the highest documented incidence of NIDDM of any population group in the world. For 20 years the Pimas have cooperated with the scientific community in Phoenix. This research has led to important insights into NIDDM.

One important goal for the scientists at Phoenix is to characterize exactly how NIDDM develops and what is involved in causing the very high levels of blood glucose seen in some people with this disease. Studies done in Phoenix suggest that the process is not a simple one. Dr. Clifton Bogardus and colleagues have described a sequence of events in which insulin resistance is an early defect. There may be a number of causes for insulin resistance. Some evidence supports the theory that insulin resistance can be compounded by an inability of the pancreas to respond appropriately to rising glucose levels. The body, unable to use glucose adequately, turns to fats for energy and the liver begins producing more glucose, exacerbating already elevated glucose levels.

Each of the steps described above may provide a point at which intervention might be aimed to help control high blood glucose in NIDDM. This research contributes to an understanding of the disease, but is also essential to developing new treatments and understanding how currently available treatments can be used to their best advantage.

Diabetes Treatment

The news that generated the most excitement in the diabetes community this year was the announcement by Drs. Paul Lacy and David Scharp at Washington University, St. Louis, Missouri, of the resumption of attempts at transplantation of insulin-producing (islet) cells into human patients. Transplantation, if successful, offers important benefits to insulin-dependent diabetic patients. Transplanted tissue would respond to the moment-to-moment fluctuations--even minor ones--in blood glucose level in a way that periodic injections cannot. If complications prove to result from fluctuations in blood glucose, transplantation could help prevent such complications while at the same time improving glucose control. In addition, transplantation would free diabetic patients from the need for daily injections.

Drs. Lacy and Scharp reported in June results with six patients who received the insulin-producing islet cells. The transplanted cells produced insulin in three of the six patients for up to 8 weeks. The scientists are optimistic that continued studies will lead to a higher success rate and longer function of transplanted cells. In addition, research is aimed at making it possible to transplant insulin-producing cells without the need for drugs to suppress rejection. This work, and much of the basic research that led up to it, was based at the NIADDK-supported DRTC at Washington University.

While insulin-dependent and noninsulin-dependent diabetes appear similar in many ways, insulin administration is optional rather than a necessity for many people with NIDDM. Recent research, however, indicates that in NIDDM patients careful insulin administration not only lowers glucose levels but also, over time, improves how body tissues respond to glucose. Grantee Dr. Orville Kolterman and colleagues at the University of California at San Diego used insulin pumps to maintain glucose levels close to normal over 3 weeks in a group of 14 patients with NIDDM. After this intense insulin therapy, body tissues were better able to metabolize glucose, the pancreas' ability to secrete insulin was improved, and glucose output in the liver was reduced to normal. These effects persisted even after the treatment ended. This research shows that high glucose levels that result from NIDDM may also increase the metabolic abnormalities in this disease. Because some of these abnormalities apparently can be reversed by bringing blood glucose back to normal with administered insulin, the work also opens up an avenue of investigation for potential therapeutic applications of this treatment.

Technology and the Future

Technological advances in the field of diabetes have furnished new devices and techniques for diabetes therapy and have greatly increased the variety and capabilities of research methods available to scientists in this field.

New therapeutic capabilities are enabling scientists to assess the relationship between careful blood glucose control and the development of complications of diabetes. This relationship poses the major current question in diabetes treatment. This year, NIADDK's Diabetes Control and Complications Trial, a clinical trial designed to answer this question, successfully completed its feasibility stage. The study organizers expect to follow the volunteers enrolled until 1993. The outcome of this study will have widespread implications for the treatment of diabetes and the outlook for reducing the long-term illness and disability this disease can cause.

New techniques in molecular biology are allowing scientists to characterize the immunologic changes that lead to IDDM and to identify genetic markers that indicate an increased sus ceptibility to this disease. This year grantees Drs. Sathyanarayana Srikanta, George Eisenbarth, and their colleagues at the Joslin Diabetes Center, Boston, reported on a study in which they are screening first-degree relatives of IDDM patients for antibodies to insulin-producing cells. These antibodies are found in IDDM patients and are a sign of immunologic activity against these cells. Out of 1,723 nondiabetic relatives of diabetic patients screened, the researchers found 16 relatives with antibodies. One of these 16 subsequently became diabetic, and 6 had abnormally low production of insulin in response to glucose. One initially nondiabetic relative who did not have antibodies also developed diabetes. This type of screening, only now possible because of techniques for detecting antibodies, may have potential for early identification of people at risk for diabetes.

Human insulin made by recombinant DNA techniques has been available for patients with diabetes since 1982. The ability to synthesize hormones has therapeutic usefulness, but it also makes possible structural and functional studies of hormones. Last year, Dr. Robert Merrifield of New York's Rockefeller University won the Nobel Prize in chemistry for developing a method to synthesize peptides, short versions of proteins. NIADDK has supported Dr. Merrifield's research for 30 years. This year Dr. Merrifield used this technique to produce purified glucagon, a hormone that has the opposite effect on glucose metabolism that insulin does. His technique enables scientists to construct glucagon molecules with structural alterations and to study how these alterations affect the function of the hormone. This technique will help us understand the function of glucagon and can provide a basis for designing new drugs that could help regulate glucose metabolism.

To fully exploit these new technological capabilities, modern facilities and expert personnel are essential. NIADDK supports seven Diabetes Research and Training Centers and five Diabetes-Endocrinology Research Centers. In addition to specialized core research facilities, the DRTC's have a training component aimed at health professionals.

Diabetes research in recent decades has led to new and effective means to control this disease and help prevent and treat its complications. There is a demonstrated gap, however, between the progress that has been made in research, and the transfer of this knowledge to primary health care practitioners who treat most patients with diabetes. Through both research on the medical care of diabetic patients and professional education, the DRTC's have developed curricula and supportive materials, such as computer programs, as resources for the instruction of health professionals in the state-of-the-art care of diabetic patients. The DRTC's have cooperated with local medical centers and health departments to make these resources readily available to the community. Thus, in addition to providing the technological base for advanced research on diabetes, the DRTC's are developing through research rapid and effective means by which new scientific information can be passed on to health professionals who can use this expertise to reduce the illness and disability associated with diabetes.

National Cancer Institute

Cancer of the pancreas, diagnosed in 25,000 Americans annually, detected until it is in an advanced stages. Although comprising only about 2 percent of all new cancer cases the disease accounts for about 5 percent of all cancer deaths. It is the fourth most common cause of cancer deaths in men and the fifth most common cause of cancer deaths in women.

Some studies have linked diabetes mellitus with pancreatic cancer, but whether common factors lead to both cancer and diabetes-like changes or if diabetes makes individuals prone to cancer is not known.

At the University of Nebraska Medical Center in Omaha, National Cancer Institute (NCI) grantee Dr. Parviz Pour is studying diabetes as a possible predisposing factor in pancreatic cancer development. Scientists have found that the chemicals alloxan and streptozotocin can induce in hamsters pancreatic cancer that resembles the human disease. In this experimental system, the cancer occurs in cells called ductular stem cells, which in normal hamsters develop into the very specialized cells of the pancreas.

In human adults that develop diabetes, the pancreas produces abnormally large amounts of ductular stem cells. Scientists have suggested that this increased cell growth might be associated with an increased risk of ductular cell cancer. In the animal model, a similar production of large numbers of ductular cells occurs, but this can be suppressed by insulin treatment. The Omaha scientists are also using animal models to study whether insulin will inhibit the development of pancreatic cancer. If successful, the results of these experiments will suggest new approaches for preventing pancreatic cancer in adult diabetics.

At the Stanford University School of Medicine, NCI and National Institute of Allergy and Infectious Diseases (NIAID) grantees Drs. Nelson N. H. Teng and Henry S. Kaplan (now deceased) and coworkers have made monoclonal antibodies that neutralize endotoxins, a family of powerful toxins produced by gram-negative bacteria. Endotoxins are found on the surface of certain bacteria such as Escherichia coli, an organism that lives in the human digestive tract. In healthy people, these bacteria are generally harmless because they are kept under control by the body's immune system.

But surgery and other diseases, including diabetes, can predispose a patient to bloodstream-borne infections called bacteremia, and the endotoxins produced by these bacteria can lead to toxic reactions. Besides diabetics, victims include premature infants and patients with cirrhosis, cancers, infections of the urinary or gastrointestinal tract, and transplant recipients.

In the laboratory, the newly produced monoclonal antibody neutralized endotoxin toxicity and prevented death from bacteremia in animals injected with a wide variety of gram-negative bacteria.

National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (NHLBI) maintains extensive research interest in diabetes as it is a known risk factor for cardiovascular diseases. An estimated 25 percent of all diabetics have some form of cardiovascular disease.

Diabetics frequently are found to have an increased level of triglycerides and other blood lipids, which may contribute to the increased level of heart attacks and atherosclerosis among them. Finding a way to reduce the level of these blood lipids could reduce the incidence of cardiovascular diseases among diabetics.

NHLBI grantee Dr. William Connor at the Oregon Health Science University in Portland has been studying the effects of various diets on blood lipid levels. He and his coworkers have found that one way to lower cholesterol and triglycerides is to eat a diet high in fish oils. In a study of 20 patients with elevated levels of triglycerides and cholesterol, those fed a diet high in the certain fatty acids found in fish oil had a much greater decrease in blood triglycerides than those fed a low-fat diet or a diet high in vegetable oils while all groups had similar decreases in blood cholesterol levels. Some patients consuming the fish oil diet experienced as much as a 79 percent reduction in blood triglycerides compared with individuals on the vegetable oil diet. The investigators concluded that a high intake of fish oils may be useful in diets to lower elevated blood lipids, a major risk factor for coronary heart disease.

NHLBI grantees at the University of Texas Health Sciences Center in San Antonio are studying diabetes and cardiovascular risk in Mexican-Americans. Dr. Michael Stern and his colleagues have formulated a new perspective on impaired glucose tolerance and its relation to cardiovascular disease. Impaired glucose tolerance (IGT) has been considered a transitional state between normalcy and diabetes. The researchers think that IGT in some populations may instead represent one of three different states.

The evidence for this interpretation lies in the bimodal distribution of glucose tolerance within certain populations. In this case, bimodality means that testing large numbers of a given population will result in a curve that shows two distinct peaks for impaired glucose tolerance: one peak clearly within the "normal" range and another, smaller one clearly elevated. The populations that demonstrate bimodality--those that are of New World or Pacific Island origin--also have a higher incidence of diabetes.

Dr. Stern theorizes that because of the double-peak distribution, IGT may mean one of three things: an individual normally has a high level of glucose and is not diabetic, is diabetic but appears to test within the high values of normal, or is indeed in transition from normalcy to a diabetic state. It is not possible to discriminate among the three states by the standard glucose tolerance test.

This finding suggests that physicians should recognize IGT not as a single entity but as any of several states, especially among certain populations. Repeat glucose tolerance tests should be performed to determine whether the patient is progressing into of diabetes or has reached a static level of high plasma glucose. Still, the traditional clinical advice to maintain ideal weight, exercise, stop smoking, and decrease the amount of saturated fat and cholesterol in the diet appears to be sound, especially since these recommendations promote overall good health. It remains for a marker to be discovered that will indicate the pre-diabetic state more certainly than IGT.

National Institute of Dental Research

The National Institute of Dental Research (NIDR) supports research on the dental complications of diabetes because persons with diabetes are particularly susceptible to periodontal diseases, oral fungal infections, reduced salivation, and diminished senses of taste and smell.

The nature of the relationship between periodontal diseases and diabetes, however, is not yet clear. NIDR-supported dental scientists from the State University of New York (SUNY) at Buffalo in collaboration with NIADDK-sponsored scientists have teamed with diabetes experts in Phoenix, Arizona, to study the Pima Indians--a native American tribe with the highest rate of diabetes in the world.

Their findings show that markedly severe periodontal diseases are common complications of NIDDM. This team also found that periodontal diseases develop at an earlier age in Pima Indian diabetics than in nondiabetics and appear to be associated with B. gingivalis, an organism suspected of causing gum disorders. One-third of the diabetic Pima Indians had lost all of their teeth; less than 2 percent of nondiabetic Pimas showed similar tooth loss. The researchers also suggested that the presence of periodontal diseases in a diabetic can complicate the management of the medical problem because bacterial infection and inflammation in the gums can interfere with the regulation of blood sugar levels.

Future studies will focus on a broader understanding of the cause of periodontal diseases, on better approaches to treatment, and on the ultimate prevention of this serious complication of diabetes.

NIDR intramural scientists continue to study the basic causes of juvenile-onset diabetes. Under the direction of Dr. Abner L. Notkins, the scientists are examining the roles of viruses and immunity in human and animal models of diabetes. They believe that some cases of diabetes involve an immunological "mistake" in which the body produces antibodies, disease-fighting proteins, against itself. Normally, immune responses destroy invading bacteria, viruses, and tumors. When misdirected, however, they can destroy the patient's own tissues. Many patients with juvenile diabetes have autoantibodies in their blood, and researchers believe that these autoantibodies can attack islet cells and possibly produce diabetes.

More recently, Dr. Notkins and his colleagues have detected these autoantibodies in healthy siblings of diabetic children from 2 to 74 months before the onset of diabetes. This is a major step in identifying persons at high risk of developing this disorder.

Diabetes patients often exhibit both thickening of the membrane just below the skin (basement membrane) and disturbances in bone formation. Intramural investigators at NIDR are currently using sophisticated monoclonal antibody and recombinant DNA techniques in efforts to understand the nature of these changes. Studies are also being conducted to test the use of antidepressants to relieve the chronic pain from nerve damage (neuropathy) associated with diabetes. Other investigators are working to characterize the specific types of sensory loss seen in diabetic patients.

National Institute of Neurological and Communicative Disorders and Stroke

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) is the focal point within the Federal Government for research on diabetic neuropathy, a serious neurological complication affecting nearly 10 percent of the more than 10 million diabetics in the United States. Symptoms of diabetic neuropathy may include burning sensations, numbness, weakness, and paralysis in the hands and feet. Some scientists think these symptoms are caused by the effect of diabetes on metabolism within nerve cells. There is mounting evidence, however, that symptoms may be the indirect result of blood vessel damage caused by diabetes. Other scientists believe diabetic neuropathy cannot be explained by any single mechanism.

Studies by NINCDS grantee Dr. Peter Dyck and colleagues at the Mayo Clinic in Rochester, Minnesota, support the damaged blood vessel theory. This year, the research team found that diabetic rats supplied with increased oxygen were slow to develop the abnormal nerve conduction characteristic of diabetic neuropathy. Furthermore, nondiabetic rats exposed to long periods of decreased oxygen developed nerve conduction abnormalities typically seen in diabetic rats. Since low oxygen levels result from decreased blood flow, this research supports the team's earlier finding that constricted blood vessels are a component of diabetic neuropathy in humans.

These researchers have now begun an epidemiological study of the prevalence of neurological complications of diabetes. They devised a computerized profile of neurological symptoms to standardize the criteria for determining disability due to such complications. One goal of this research is to identify similarities among patients afflicted with diabetes complications.

Unexpected information about diabetics has emerged from studies at the NINCDS-supported Clinical Smell and Taste Research Center at the University of Pennsylvania in Philadelphia. Drs. James Snow and Gregg Settle and their colleagues found that in a taste test, diabetics and their nondiabetic relatives recognized the taste of the glucose less readily than they did the sugar fructose. In contrast, glucose recognition was significantly stronger than fructose recognition in people who had no diabetes and no family history of the disease. These results suggest that a general lack of glucose recognition may underlie NIDDM. The data also suggest that glucose may have a taste recognition mechanism distinct from that of fructose and other sugars.

At the Michael Reese Hospital and Medical Center in Chicago, Illinois, NINCDS grantee Dr. Dale Pelligrino is studying the role of insulin in regulating brain metabolism. In studies of experimentally induced diabetes in goats, Dr. Pelligrino discovered that this animal's metabolic responses differed from those of dogs and humans. These findings rule out goats, and probably other cud-chewing animals, as models for diabetes studies.

The National Institute of Allergy and Infectious Diseases

The NIAID has a vital interest in the medical problems confronting diabetics. Infections occur more frequently and in more serious forms in diabetics, as a group, than in the general population. NIAID's studies on infectious diseases are making significant contributions to the treatment of diabetics for these life-threatening infections.

NIAID grantee Dr. Richard D. Diamond, at Boston University School of Medicine in Massachusetts, is conducting research on two infections--aspergillosis and mucormycosis. These infections generally occur in patients with depressed immune systems. Although aspergillosis and mucormycosis are both caused by fungi, which induce very similar reactions when invading tissues of infected patients, very different groups of patients tend to develop these two infections. Specifically, mucormycosis is a serious, usually fatal, infection that characteristically develops in patients with poorly controlled diabetes. However, diabetics do not seem to be at high risk for developing aspergillosis.

These often fatal infections are increasing in importance because the number of susceptible patients is growing, either because they have a variety of diseases that affect immunity, or because they are receiving immunosuppressive therapy. Besides their intrinsic importance, these infections provide very useful models for understanding why specific predisposing conditions make some patients more likely to develop one particular infection rather than another.

Over the past 3 years, Dr. Diamond and his colleagues have studied the similarities and differences between the two infections in two groups of experimental animals (diabetic or cortisone-treated mice) and in patients with diabetes. The researchers are defining some of the specific reasons for the particular susceptibility of diabetics to mucormycosis and the tendency of immunosuppressed patients to develop aspergillosis. They have identified differences in specific properties of the microorganisms and the way they interact with specific factors in blood as well as with macrophages in the lungs, the cells that form a major first-line of defense against inhaled organisms. They are now working on defining these factors further.

Not only is this research providing useful information directly related to two important fungal infections, but it is also providing insights into why diabetics are at increased risk for developing specific types of infections. Ultimately, this information may enable scientists to treat or to prevent the complications of diabetes.

The National Institute of General Medical Sciences

The National Institute of General Medical Sciences (NIGMS) supports basic research and research training that provide the foundation for a better understanding of fundamental life processes. This research supplies new knowledge, theories, and concepts for the disease-targeted programs of other NIH Institutes. The outlook for a host of diseases, including diabetes, will be improved by NIGMS-supported studies.

Wound healing is a major clinical problem in diabetic patients. Wound infection rates are three times greater in diabetics than in healthy people, and failure to heal occurs very often in diabetics. To learn more about the biochemical basis of this problem, NIGMS grantee Dr. Thomas Hunt at the University of California, San Francisco, has compared the relationship of abnormal metabolism to healing in diabetics.

Working with insulin-deficient rats, Dr. Hunt found indications that poor wound healing may be related to lack of insulin. He also found that insulin replacement, when given early, restored healing to normal in these rats. However, in another study using obese rats, insulin therapy did not improve wound healing. Dr. Hunt is now studying non-obese human diabetics and so far his research seems to confirm the observation in rats--that well-controlled diabetics can be expected to heal as well as healthy subjects. Studies on obese human diabetics have not yet been performed.

NIGMS also provides several contracts for resources to facilitate basic research. One of these contracts supports the collection of information on the exact composition of genes (segments of the genetic material DNA). This type of information is crucial to understanding genetic processes and diseases. Knowledge of the sequence, or order of subunits, of the genes that code for important substances such as human insulin can help researchers learn more about the genetic mechanisms of disease by studying sequence variations and similarities in different species.

In recent years, new analytic techniques have led to a virtual explosion of data concerning the structure of DNA and a related molecule, RNA. For this reason NIGMS, with the cosponsorship of other Federal agencies, awarded a contract in 1982 to Bolt Beranek and Newman, Inc., of Cambridge, Massachusetts, to establish a genetic sequence data bank, called GenBank®. Sequences are collected, verified, and annotated for sites of biological interest at the Los Alamos National Laboratory. The data are then forwarded to Cambridge, where they are entered into a computer for rapid retrieval and distribution to interested scientists. This resource allows researchers to study the exact sequences of different genes, examine the role of mutation in disease states, and understand better how certain genes may have evolved.

GenBank® now has 24 entries of insulin sequences from species that include fish, chickens, rats, and humans. Some synthetic insulin sequences are also listed.

As a further means of facilitating research on diabetes and other disorders in which heredity plays a part, NIGMS also supports by contract the Human Genetic Mutant Cell Repository at the Institute for Medical Research in Camden, New Jersey. The repository establishes and stores cultured cell lines collected from patients with well-characterized genetic disorders as well as from members of their families and from normal volunteers. These cells are provided at a modest charge to scientists requesting them, thus permitting the researchers to study the cellular aspects of many genetic disorders without first having to locate a cell donor.

During the past year, the repository has established cell lines from 43 normal and affected individuals in an extended family with maturity onset diabetes of the young (MODY). In recent years scientists have been successful in correlating inherited variations in DNA sequences, called restriction fragment length polymorphisms (RFLP's), with the expression of a genetic defect. The availability of cell lines from extended families is essential for such studies. The MODY collection should be valuable to investigators searching for linkage of the gene or genes associated with this form of diabetes and for localizing and cloning these genes. Such studies may ultimately lead to diagnostic tests and therapy for this and related disorders.

The repository also has cell lines from smaller families with juvenile-onset diabetes and from diabetic Pima Indians. At present, the repository maintains a total of 130 lines of cells from diabetic patients and their families.

National Institute of Child Health and Human Development

A very high incidence of congenital malformations occurs in infants born to women with diabetes mellitus, and the frequency of these malformations has risen. They are now the leading cause of perinatal mortality in the diabetic pregnancy. The wide variety of diabetes-induced abnormalities includes heart, neural tube, vertebral, and limb malformations. Macrosomia (overly high birth weight), late intrauterine death, and respiratory distress syndrome are also significant problems among diabetic pregnancies. In addition, pregnancy itself sometimes prompts in the mother development of either a temporary metabolic disturbance, known as gestational diabetes mellitus, or long-term diabetes. The National Institute of Child Health and Human Development (NICHD) supports four Perinatal Emphasis Research Centers in the area of diabetes.

By electronically monitoring fetal heart rate and movement, researchers have been able to examine fetal cycles. Active and quiet periods lengthen with age in normal fetuses. This is not the case with the fetuses of insulin-controlled diabetics, suggesting a delay in maturation.

Several groups of investigators supported by NICHD contracts and grants are examining the mechanisms by which diabetes interferes with normal fetal growth. Hyperglycemia (too much glucose in the blood), excessive amounts of chemical compounds known as ketones, and the presence of hormones inhibiting the production of the growth-mediating hormone somatomedin have all been shown to independently interfere with normal development. Using culture techniques, researchers are studying the effects of these factors on rat and mouse embryos. Defining the biochemical alterations produced will provide a better understanding of how maternal diabetes produces birth defects.

Home monitoring of glucose levels by pregnant diabetics is being analyzed in relation to the frequency of poor pregnancy outcome in a study of more than 900 women. The Diabetes in Early Pregnancy Project is the first large-scale study to enroll women before or immediately after conception and to examine the risks of fetal loss and congenital malformations prospectively. Early enrollment is particularly important because most fetal malformations are determined in the first 6 weeks after conception. When their pregnancy was confirmed, the diabetic women had a health assessment and began daily home monitoring of their glucose levels. Blood was analyzed weekly. Preliminary data show that spontaneous abortions are not more common among these well-controlled diabetics than among control women. Comparisons of malformations in pregnancies that went to term are now being analyzed. Five medical centers are participating in this project, which is being coordinated by Dr. James Mills, an NICHD intramural scientist.

Grantee Dr. Fredda V. Ginsberg-Fellner and colleagues at the City University of New York have shown that intensive home glucose monitoring affects the birth weight of babies born to diabetic women. Two groups of pregnant diabetics were studied. A control group followed conventional treatment guidelines. The other group performed both fasting and after-meal glucose monitoring so that a need for insulin could be identified quickly. It was found that macrosomia was four times more common among babies born to women in the control group.

NICHD is also involved in applying computer technology to help diabetics monitor themselves. Dr. David Rodbard, NICHD intramural scientist has developed a number of innovative programs that can be used on home computers. Graphs and statistical displays are accompanied by detailed written descriptions, that give reasons for suggested changes in diet or in insulin dosage, timing, or type. The patient is also advised when to call the physician. Customized treatment plans can be computed, and a patient's glucose profile can be analyzed in terms of daily or weekly changes. The programs are now being evaluated in controlled clinical trials at medical centers throughout the Nation, with special emphasis on their use for children, adolescents, and pregnant women.

The relationship between the use of oral contraceptives and diabetes is also under study. As part of an NICHD contract headed by Dr. Thomas B. Clarkson at Wake Forest University in Winston-Salem, North Carolina, oral glucose tolerance tests and insulin assays are being administered to oral contraceptive users, who are classified as short-, intermediate-, or long-term users of either high- or low-dose preparations. A sample of women are being given intravenous glucose tolerance tests to determine whether impaired glucose tolerance in oral contraceptive users results from insulin resistance or impaired production of insulin. A second contract study will be undertaken to corroborate the results from the first. Comparisons of users of all oral contraceptive compounds will be provided through one of the world's largest metabolic data bases, located in England. Because of its size and prospective design, the English study should clearly identify time and dosage trends in metabolism. These studies will provide information on precisely how contraceptive steroids alter metabolism, contributing to an understanding of their diabetes-inducing potential.

Other research is aimed toward discovering a marker that can be used to indicate latent IDDM among the general population. The presence of islet cell autoantibodies (antibodies that are directed against the body's own cells) has been suggested as such a marker. In a study of school children, grantee Dr. Noel K. MacLaren and colleagues at the University of Florida at Gainesville found that such antibodies are indeed found only among children who are genetically susceptible to IDDM.

Dr. Ginsberg-Fellner at the City University of New York is also studying the presence of antibodies against insulin in the blood of children who are developing IDDM. Blood is tested when the diabetes is diagnosed as well as during the development of the disease. It has been determined that these antibodies are present at the onset of diabetes in most of the children. The researchers suggest that insulin may be released in a form that stimulates the immune system to attack it just before the onset of symptoms of diabetes. Similar findings were noted by grantee Dr. Lori Laffel at the Children's Hospital in Boston, Massachusetts, in her study of antibodies against insulin and insulin receptors among diabetics, prediabetics, and patients with insulin allergy.

The pancreatic islet cells of insulin-dependent diabetics malfunction, and transplantation of normally functioning islets has been suggested as a possible treatment. Grantee Dr. Alyne Ricker, also at Boston Children's Hospital, is working to protect transplanted insulin-secreting tissues from host defenses by microencapsulating the transplanted cells. This technique has effectively reduced hyperglycemia in diabetic mice grafted with insulin-secreting cells.

National Eye Institute

Diabetes is responsible for loss of vision in thousands of Americans each year. In fact, it is the leading cause of new cases of blindness in people 20 to 74 years old.

Over a period of years, diabetes causes a series of harmful changes in the retina, the delicate light-sensing tissue lining the inside of the eye. The resulting visual loss may be profound, as it often is when diabetic retinopathy progresses to the point where hemorrhaging prevents incoming light from reaching the retina. Or, the visual deficit may be much less severe, as in diabetic macular edema when excess fluid swells retinal tissue, blurring vision. But even this milder degree of impairment can dramatically affect the quality of life for the diabetic person whose visual acuity has declined just enough to prohibit reading or driving a car.

The National Eye Institute (NEI) supports research aimed at overcoming the full spectrum of diabetes-induced ocular problems, which are believed to affect as many as 40 percent of our Nation's 10 to 11 million diabetics.

In one NEI-supported clinical trial, the Early Treatment Diabetic Retinopathy Study (ETDRS), laser treatment is being evaluated in patients who are mildly affected, i.e., still in the early stages of diabetic eye disease. Recent results from this study show that it is possible to halt or even reverse the mild to moderate reduction in visual acuity that afflicts many people with diabetic macular edema.

At the beginning of the study, eyes with macular edema were randomly assigned to receive either immediate or deferred treatment. Eyes in the immediate treatment group underwent focal photocoagulation with the argon laser. The objective is to coagulate only the tissue suspected of leaking fluid into the macula, thereby causing retinal swelling. The technique differs from the more extensive laser treatment employed in the previously reported Diabetic Retinopathy Study (DRS). In the DRS, panretinal photocoagulation was evaluated in people with advanced diabetic retinopathy. It was found to be effective in preventing severe visual loss and blindness caused by abnormal development of retinal blood vessels.

In the ETDRS, a total of 1490 eyes were assigned to the deferred treatment group while 754 received immediate focal photocoagulation. At 3 years, 24 percent of eyes in the untreated group had lost a significant amount of visual acuity, whereas only 12 percent of those in the treated group had done so. Focal treatment also increased the chance of visual improvement, decreased the frequency of persistent macular edema, and caused only minor visual field losses. The beneficial effects of treatment led the ETDRS investigators to recommend that all eyes with significant macular edema be considered for focal photocoagulation.

These recent findings from the ETDRS will result in a substantial increase in the number of diabetics who are eligible for some type of laser treatment to preserve their eyesight and who require regular eye examinations to find out if treatment is indicated. This means primary care physicians will have to play a more active role in referring their diabetic patients to specialists trained to diagnose and treat diabetic eye disease. For not only do we know how to prevent severe visual loss associated with advanced proliferative retinopathy, we now know how to combat the milder though still disturbing effects of diabetic macular edema.

There was good news this year also for diabetics who have experienced one of the most devastating events in the progression of diabetic retinopathy--a severe vitreous hemorrhage. This occurs when abnormal new blood vessels growing from the retina rupture and bleed into the vitreous. When vitreous, normally a clear gel that fills the center of the eyeball, becomes clouded with blood, vision is obscured. In addition, scar tissue may form and cause detachment of the retina. Again, permanent visual loss, even total blindness, may result.

In the NEI-supported Diabetic Retinopathy Vitrectomy Study (DRVS), two approaches to surgical restoration of sight were compared in people who had suffered a vitreous hemorrhage causing serious loss of vision. The surgery, called vitrectomy, involves removal of the blood and scar tissue from the center of the eye. Early vitrectomy was compared to deferred vitrectomy to find out if better visual results can be achieved by operating soon after the hemorrhage has occurred or by waiting a year in hopes that the hemorrhage will clear on its own.

In the DRVS, 616 eyes with a hemorrhage that had caused a dramatic reduction in visual acuity for at least a month were randomly assigned to one of the two treatment groups. At the 2-year followup examination, the investigators found that 24.5 percent of eyes that underwent early vitrectomy had a visual acuity of 20/40 (driving vision in most states), while only 15.2 percent of those in the deferred treatment group had achieved such acuity. The beneficial effect of early treatment was more apparent in those patients who had type I (juvenile-onset) diabetes. In these eyes, 36 percent of the early vitrectomy group, compared to 12 percent in the deferred vitrectomy group, had a visual acuity of 20/40 or better after 2 years. The investigators concluded that early vitrectomy can improve chances of long-term recovery of good vision in some eyes.

The NEI is concerned not only with appropriate management of diabetic eye disease once it develops, but also with its prevention. In one ongoing multicenter study involving 600 insulin-dependent diabetics, a new drug is being evaluated to determine whether it can protect the retina from diabetes-induced damage. The NEI is sponsoring the Sorbinil

Retinopathy Trial in collaboration with Pfizer, Inc., the pharmaceutical firm that developed the drug being tested. Half of the patients will receive the drug sorbinil and half a placebo to determine if the drug can prevent or slow down the development of diabetic retinopathy in people who are known to be at high risk for this disorder but do not yet show serious signs of eye disease. During the past year, efforts to recruit patients were expanded and the number of patients enrolled increased dramatically.

The NEI also supports a wide range of research projects conducted by a diverse army of basic scientists and clinical investigators dedicated to fighting the ocular complications of diabetes. Thanks to their efforts and the efforts of researchers participating in NEI-supported multicenter clinical trials described above, millions of Americans with diabetes will be able to avoid many of the ocular complications of this disease and enjoy good vision throughout their lives.

National Institute of Environmental Health Sciences

Dr. Brooke Mossman, a National Institute of Environmental Health Sciences (NIEHS) grantee, and her colleagues at the University of Vermont College of Medicine in Burlington are studying how n-nitroso compounds a broad class of chemicals that are ubiquitous, in the environment, damage insulin-producing cells. Among these compounds for example is Vacor®, a rodenticide known to caus diabetes in man. In recent studies, these researchers have examined whether cell damage induced by two n-nitroso compounds, streptozotocin (SZ) and chlorozotocin (CLZ), involves oxygen-free radicals extremely reactive groups of atoms. To address this question, they evaluated compounds that are scavengers of oxygen-free radicals. These radical scavenger compounds were tested for their ability to prevent SZ- or CLZ-induced damage to insulin-producing cells in the laboratory. The data indicated that a dual mechanism involving both the generation of certain radicals and the activation of a particular biochemical pathway, the poly(ADP ribose) system, may promote SZ-induced toxity of insulin-producing cells. Injury to insulin-producing cells by CLZ, on the other hand, could not be prevented by any of the free radical scavengers tested or by inhibitors of the enzyme that activates the poly(ADP ribose) pathway. Specialized blood cells are now being studied as a possible intermediary cell in this disease. Dr. Mossman and her colleagues are also looking at whether the insulin-producing cells are capable of repairing themselves after interaction with diabetogenic chemicals. The investigators have examined the interaction of SZ and CLZ with the DNA of insulin-producing cells using a sensitive technique to determine DNA damage. Both CLZ and SZ have been found to cause significant but different types of damage to DNA. Further experiments are planned to determine whether this damage is "repaired" with time in pancreatic cell tumors, in normal pancreatic beta cells, and in connective tissue cells, or fibroblasts. The results to date from comparative studies with fibroblasts suggest that the beta cell's repair capacity is minimal.

Finally, this team of investigators has collected data suggesting that the association between the n-nitroso moiety and a particular carbon atom of glucose is important in eliciting cell injury. By modifying the structure of or removing the glucose in n-nitroso compounds, diabetogenicity is prevented.

Grantee Dr. Glenn L. Wilson and colleagues at the University of South Alabama College of Medicine in Mobile have been using tissue culture techniques to study chemicals that cause diabetes. The investigators have examined how free radical scavengers influence the effects of the insulin-producing cell toxin, alloxan. It was found that two scavengers reduced the toxic effects of alloxan. In addition, inhibitors of the enzyme that activates the biochemical pathway implicated the SZ-induced toxicity effectively reduced alloxan-induced beta cell toxicity. The investigators believe that the initial step in SZ-induced insulin-producing cell toxicity is the alkylation of DNA bases leading to DNA damage. However, no studies have quantitatively evaluated the extent of DNA damage in insulin-producing cells and correlated this damage with toxicity. Therefore, these two parameters were compared following exposure of rat insulin- producing cell cultures to SZ or another n-nitrose compound, n-methyl-n-nitrosourea (MNU). Although SZ was 10 times more toxic than MNU with respect to insulin production, both compounds had similar effects on DNA. These data indicate that it is not simply the damage to the DNA that lead to the toxicity of SZ, since MNU causes comparable DNA damage at a non-toxic concentration (i.e. no effect on insulin release).

One consequence of diabetes is a change in the way the liver metabolizes environmental compounds. Grantee Dr. David Cook and his associates at the University of Nebraska Medical Center in Omaha have begun a new study relating this altered metabolism in the liver to the reaction of diabetics to toxic environmental chemical exposure. An understanding of these relationships is important to those who oversee the care of diabetic patients and to those interested in the hormonal regulation of biochemical processes. Since certain specialized proteins are important in such processes, these investigators are developing antibodies monospecific to these normal and diabetic proteins found in the liver, which may appear in diabetes mellitus. Characterization of this enzyme may clarify the mechanism that causes an other than normal metabolism of drugs in the livers of diabetics.

National Institute on Aging

One of the most frequently occurring disorders associated with old age is diabetes mellitus. Scientists do not fully understand all the biochemical and physiological changes that contribute to the development of diabetes, and it is sometimes difficult to distinguish these changes from those occurring normally with age, such as decreased glucose tolerance. The National Institute on Aging (NIA) supports research to determine the underlying mechanisms involved in diabetes, to develop improved methods of diagnosis and treatment, and to investigate the behavioral and psychosocial impact of diabetes on elderly patients and their families.

Noninsulin-dependent diabetes (NIDDM) is the more common form of the disease in older adults. Many investigators have attempted to resolve two fundamental questions about NIDDM: Does it represent a defect in insulin production, insulin release, or insulin action at the cellular level, or is it the result of phenomena that occur as part of the aging process?

NIA grantee Dr. Byron Hoogwerf and his colleagues at the University of Minnesota in Minneapolis are studying age-related changes in pancreatic beta cells as a means of providing insight into diabetes mellitus in older adults. The researchers are using a simple noninvasive test to determine insulin production in humans. C-peptide is a compound secreted from beta cells in direct proportion to insulin secreted from beta cells. It was previously shown that insulin production can be determined by measuring the excretion of C-peptide in the urine.

By evaluating C-peptide levels in both diabetic and nondiabetic individuals under a variety of dietary conditions, Dr. Hoogwerf has shown that there seems to be an increase in C-peptide production, and therefore insulin production, with increasing age. Nevertheless, in some older subjects this response is insufficient to keep the response to glucose in the range of that seen in younger subjects.

In another NIA-supported study on diabetes mellitus, biochemist Dr. Charles Howard and colleagues at the Oregon Regional Primate Research Center in Beaverton, Oregon, have been working with a species of monkey (Macaca nigra) that is a particularly good research model because over 70 percent of them will develop diabetes spontaneously as they age. Thus, researchers need not use experimental methods to induce diabetes but can study the natural development of the disease in a species closely related to humans. By studying these monkeys over their normal lifespan, investigators can monitor the early stages of diabetes, with the goal of uncovering possible interventions.

Antibodies to pancreatic islet cells (ICA) have been identified in the blood of aging prediabetic and diabetic M. nigra in association with islet cell degeneration. The presence of ICA was found to be correlated with both metabolic status and morphological changes in the islet cells. Eighty-seven percent of nondiabetic monkeys were ICA-negative; more than 90 percent of monkeys with mild to severe hormonal or glycemic (glucose) abnormalities were ICA-positive. More than 80 percent of the monkeys with any evidence of islet cell deterioration from samples examined at the time of autopsy or biopsy were also ICA-positive. From these findings, Dr. Howard has concluded that the presence of ICA in the blood strongly indicates the presence of islet cell lesions, and the loss of cells due to these lesions can cause further carbohydrate impairment.

In general, IDDM in humans is associated with beta cell necrosis while NIDDM diabetes involves defects in insulin secretion or resistance to insulin action. However, many maturity-onset cases do not fit this simple categorization. Although ICA have been found in patients with NIDDM, islet cell degeneration has not been an accepted characteristic of this type of diabetes. Using data from M. nigra, along with data from other relevant studies, it may be possible to explain this discrepancy, delineate a major form of maturity-onset diabetes, and improve therapy.

The potential significance of Dr. Howard's work is that, by using a simple blood test, physicians may be able to identify a subpopulation of individuals with NIDDM. Treatment initiated in the very early stages of the disease may help prevent further cell damage.

Cell culture studies are also important in research on diabetes. To date, only a few normal cells have been successfully cultured as models for studies of aging. Scientists have been able to culture abnormal (that is, cancer) cells, but such cells do not allow investigations into the normal changes that occur with aging. Now, Drs. Lu Zhongding and Robert Gregerman and colleagues at the NIA's Gerontology Research Center (GRC) in Baltimore, Maryland, have succeeded in culturing normal mature fat cells (adipocytes).

Scientists had previously assumed that mature fat cells would not divide under laboratory conditions. But after success in culturing preadipocytes (precursors of fat cells), the GRC investigators succeeded in isolating and then growing mature fat cells. They are using these cells to determine whether the age of the donor animal programs the adipocytes to exhibit in cell culture the same type of biochemical change that occurs in the living animal. This work may provide scientists with a new cell type that will enable them to study measurable biological and molecular events. This, in turn, may help researchers determine how and why age-related changes, such as glucose intolerance, occur. For example, cellular changes in fat cells may be the result of genetic programming or, n the other hand, the secondary consequences of environmental conditions.

Division of Research Resources

Significant strides toward achieving the promise that pancreas transplantation holds as a treatment for the thousands of diabetics who are likely to develop blindness or other devastating complications of their disease have been made by Dr. David Sutherland and colleagues at the University of Minnesota General Clinical Research Center (GCRC) in Minneapolis. The University of Minnesota GCRC is one of more than 72 such centers studying diabetes.

Nearly a third (32 patients) of the 103 patients who have received pancreas transplants since 1978 have shown signs of long-term engraftment and no longer require insulin, including 18 who have been insulin independent for more than one year. During 1985 the success rate increased to 64 percent, with engraftment occurring in 14 of 22 diabetics who underwent transplantation. Moreover, Dr. David Sutherland and his team have documented regression of kidney disease in four transplant recipients who have been insulin independent for more than one year.

These developments brighten the prospects for diabetics who cannot achieve reasonable control of their blood sugar levels with the standard regimen of insulin injections, dietary management, and exercise. High blood sugar levels--perhaps in combination with other factors--progressively damage the blood vessels and nerves, causing heart and kidney failure, blindness, and other complications.

Among the many complications that can afflict diabetics is rheumatic hand syndrome, which can transform simple tasks into ordeals. Progressive stiffness and loss of sensation in the hands may prevent affected diabetics from performing job-related duties, jeopardizing their livelihood. At the University of New Mexico GCRC in Albuquerque, researchers led by Dr. R. Philip Eaton administered the new drug sorbinil to three diabetics with rheumatic hand condition.

After a month of sorbinil therapy, all three patients were able to hold and use their insulin syringe, a task that had been impossible for them before treatment. Continued treatment allowed one patient to resume performing all of her duties as a nurse, from measuring blood pressure to administering medication. All three patients regained the ability to write, and one reported being able to tie flies to a fishing line. In followup studies of two patients, the researchers found that sorbinil therapy also improved nerve conductivity and restored sensation in their hands.

Sorbinil inhibits the activity of an enzyme that participates in the synthesis of sugar alcohols. By interrupting this biochemical pathway, Dr. Eaton speculates, the drug may prevent the abnormal accumulation of alcohols and the consequent swelling of connective tissue, which is suspected of causing joint stiffness.

In addition to medication and diet, exercise is a fundamental component of therapy for diabetics. A mix of continuous and intermittent exercise, the kind typical of such childhood games as tag and soccer, reduce blood sugar levels in insulin-dependent diabetic children, according to the first phase of research being conducted by DRR grantee Dr. Irene N. Sills in New York at The Children's Hospital of Buffalo.

The finding, based on a study of five boys with IDDM, is a first step toward filling the large void in information about how exercise affects young diabetics. Dr. Sills notes that exercise often is recommended to improve glucose tolerance in IDDM patients. These recommendations, however, are based on studies of diabetic adults who engaged in continuous forms of exercise such as running, bicycling, and swimming.

OUTLOOK

As the Institute reports illustrate, research on diabetes is advancing on many interrelated fronts. While each Institute supports research that ostensibly deals with that Institute's own health territory, for example, the eye or cancer, no one can predict all the fields that a given research advance may affect. One reason for this is that diseases like diabetes affect many different systems and organs. More important, basic biomedical investigation, an emphasis of all the National Institutes of Health, provides an understanding of how living organisms function in normal and disease states. Without this context of understanding to point the way to possible new treatment approaches, clinical research would be a hit-or-miss process. Without the methods developed in basic, often undirected, research, investigation of specific defects such as those associated with diabetes would be much slower, if not impossible.

CENTERS FOR DISEASE CONTROL

Diabetes Control

There are 5.8 million people with known diabetes in the United States. There may be an equal number as yet undiagnosed; and annually over 300,000 persons with diabetes die. Diabetes consumes 25 million hospital days and costs nearly $8 billion in direct medical expenditures annually. It is a disease which requires the patient to assume major responsibility for his/her own care. It cannot be cured, but sufficient knowledge is available to prevent or delay its costly complications.

In an effort to improve outcomes, CDC, in partnership with 25 States, has conducted a wide range of activities aimed at (1) developing effective control strategies at the community level, (2) establishing consensus concerning standards for patient management and self care, (3) developing networks for rapid translation of advances in care into community practice, and (4) creating the operational base upon which these strategies can be built.

FORESTALLING CHRONIC COMPLICATIONS

Preventing Visual Loss

Diabetes is the leading cause of blindness in adults under 75, and 60 percent of that blindness can be prevented with timely identification of diabetic eye disease and appropriate therapy. Twelve States, funded by CDC, are undertaking blindness prevention programs. These programs include screening of diabetic patients for eye disease with fundus photographs taken by well-trained, non-physician health professionals; development of guidelines for appropriate referral and eye care; assessment of current eye care practices; and assurance that necessary treatment is provided. A pilot study has been conducted of the skills of optometrists in examining the eyes of persons with diabetes, and the data are being analyzed. As many as 8 percent of persons examined have required urgent treatment to prevent visual impairment.

Preventing Amputations

Half of all non-traumatic amputations performed in the United States each year are due to diabetes. Good foot care can reduce this burden by 50 percent. Several CDC projects have focused efforts in this area including studies to examine approaches to patient education for improving foot care, to identify risk factors and populations at risk for amputation, and to evaluate running shoes as an acceptable alternative to expensive prescription footwear.

Preventing Poor Pregnancy Outcomes

Diabetic women who become pregnant have a four to six-fold increased risk of having infants with major congenital anomalies. Approximately 850 infants are born each year with major anomalies due largely to elevated glucose levels during the first 12 weeks of pregnancy. As many as 500 of these are preventable if women with known diabetes achieve normal blood glucose prior to conception and maintain it throughout pregnancy. Recent improvements in blood glucose control techniques permit this goal to be realized. Demonstration programs are now underway to identify and treat women of childbearing age with diabetes prior to conception and throughout pregnancy. In one study, major congenital anomalies occurred in 16 percent of the offspring of women beginning care in the first trimester, compared to 2 percent of offspring of women beginning care prior to conception. Other studies are being conducted to provide population-based estimates of the impact of gestational diabetes.

IMPACT ON RISK FACTORS

Hypertension among persons with diabetes is associated with retinopathy, end-stage renal disease (ESRD), and arteriosclerotic cardiovascular disease (ASCVD). Diabetes is a leading cause of new cases of ESRD in the United States which is one of the more costly complications of diabetes. Control of hypertension can help delay the onset of ESRD. ASCVD (myocardial infarction, stroke, peripheral vascular disease) is the leading cause of death among persons with diabetes. An estimated 45 percent of the coronary heart disease, 85 percent of the cerebrovascular disease, and 60 percent of peripheral vascular disease can be prevented with known technologies such as the treatment and control of hypertension, smoking cessation, exercise, weight loss, and prudent diet. Public health strategies have been developed to address the problem of co-existing diabetes and hypertension, and several programs are currently being implemented to reduce the prevalence of hypertension among persons with diabetes.

CONTROLLING ACUTE COMPLICATIONS

Seventy percent of the 75,000 admissions to hospitals for diabetic ketoacidosis and coma can be prevented by changing patient behaviors and by improved management of blood glucose using existing technologies. Hospitalizations have been reduced by targeting patients with Type I diabetes with a systematic education program, the use of home blood glucose monitoring equipment, and suitable professional management of blood glucose.

FORGING LINKAGES

Each of the 25 Diabetes Control Program States has developed a network for efficiently translating control strategies. These networks include advisory committees representing a wide range of public, private, and voluntary organizations. The core of the translation process is education--changing the knowledge, skills, beliefs, and practices of patients and providers.

In cooperation with various interested groups and individuals, the diabetes control program has helped develop "tools" for use in program development at State and local levels and in diabetes education projects. Examples of such tools are: The Prevention and Treatment of Five Complications of Diabetes, A Guide for Primary Care Practitioners; the National Standards for Diabetes Patient Education Programs; the Diabetes Program Handbook; and the CDC-State Diabetes Control Program Patient and Professional Education Guidelines.

Comprehensive public health strategies have been developed for each of the major complication areas.

State diabetes control programs are linking their efforts with service delivery programs and with other chronic disease programs within their State health agencies. Guidelines for enhancing diabetes control through maternal and child health programs have been developed.

BUILDING THE KNOWLEDGE BASE

A national epidemiologic investigation of mortality associated with the use of continuous subcutaneous insulin infusion (CSII) pumps was conducted. There was no increased mortality among pump users.

An epidemiologic model for diabetes mellitus describing incidence, prevalence, and mortality among Type I and Type II diabetics has been developed. It has served to integrate and document current knowledge of the occurrence of diabetes. Outcome indicators have been developed to measure the impact of programs on morbidity and mortality.

PLANNING FOR THE FUTURE

In 1986 the 20 State-based projects will complete the final year (funded from 1985 funds) of the current cooperative agreements. Interventions and special studies conducted in those 20 States will be analyzed and the results compiled for use in future diabetes control activities. Tools, knowledge, consensus, and experience now exist to enable States and communities to focus efforts in a more comprehensive fashion. The CDC program has provided funds to five currently funded States and to an additional five States to focus on diabetic eye disease as part of comprehensive care programs.

In 1985 the program developed outcome indicators for diabetes control programs. As this information is collected over time, it will serve as a benchmark for the program as it begins a transformation from a series of diverse interventions and studies into a cohesive prevention effort. The new focus will be on the major complications and associated risk factors which accelerate the occurrence and severity of those complications.

Through its intervention activities, CDC has been able to bring state-of-the-art care to selected diabetic populations. Future statewide control efforts will narrow the gap between the current state of knowledge and the current state of health.

Many of CDC's interventions have been successful in encouraging third-party payers to participate in the interventions and in developing mechanisms for financing quality care for persons with diabetes. The fruits of these activities will make quality health care available to many more persons with diabetes.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

DIABETES

Information from the national vital statistics system indicates that diabetes mellitus was the seventh leading cause of death in the United States in 1983, accounting for over 36,000 deaths or 1.8 percent of all deaths in the year. Since 1978 the risk of death for this cause has levelled off from an earlier downward trend. The risk of death from diabetes is about the same for males as for females, but over twice as high for the black as for the white population.

The basis for determining the total prevalence of diabetes mellitus in the United States adult population 20-74 years of age was obtained for the first time in the second program of the National Health and Nutrition Examination Survey as an aid to the increased authority of the National Institutes of Health and Centers for Disease Control (Public Law 93-354) for diabetes prevention, control, research and training. The diagnoses for the prevalence estimates will be obtained from the physical examination; medical and dietary history; and blood and urine tests conducted as part of the diagnostic glucose tolerance test given to a probability sample of those adult examinees not presently taking insulin. Preliminary findings indicate that the total prevalence of diabetes is approximately 50 cases per 1,000 population, or two times that for known diabetes. Similar data were collected in the Hispanic Health and Nutrition Examination Survey.

In 1976, the National Health Interview Survey (NHIS) collected prevalence data on diabetes by numerous demographic population characteristics. In addition to determining the prevalence of known diabetes in the population, the 1976 NHIS asked for the type of medication and level of knowledge about this condition among individuals reported to have diabetes. Diabetes prevalence data are collected on a continuous basis by the NHIS. Based on data now available from the NHIS, in 1983 nearly 5.6 million persons in the civilian, noninstitutionalized population were reported to have known diabetes, reflecting a rate of 24.5 conditions of known diabetes per 1,000 population. Further analysis of these and other diabetes-related data are currently in progress and are being carried out jointly with the National Diabetes Data Group and the National Diabetes Information Clearinghouse, located within the National Institute of Arthritis, Diabetes, Digestive and Kidney Diseases of NIH.

According to the 1984 National Hospital Discharge Survey, an estimated 593,000 patients were discharged from short-stay hospitals in the United States with a first-listed diagnosis of diabetes mellitus. The average length of stay for these patients was 8.2 days. Females accounted for 60 percent of the discharges and patients 45 years and over accounted for 72 percent of the discharges. In addition to those patients with a first-listed diagnosis of diabetes mellitus, an estimated 2.3 million patients were discharged with a secondary diagnosis of diabetes mellitus.

DIGESTIVE DISEASES
Obligations

	1983 Actual	1984 Actual	1985 Actual	1986 Appropriation	1986 Available After Sequestering	1986 Revised Estimate	1987 Estimate
Public Health Service:							
National Institutes of Health:							
National Institute of Diabetes and Digestive and Kidney Diseases..	$53,550,000	$63,021,000	$75,415,000	$79,400,000	$76,000,000	$74,800,000	$73,300,000
National Cancer Institute........	32,961,000	55,230,000	60,369,000	68,400,000	66,800,000	59,600,000	57,800,000
National Institute of Dental Research.........	609,000	635,000	1,952,000	2,342,000	2,241,000	2,241,000	2,150,000
National Institute of Allergy and Infectious Diseases.........	20,513,000	25,955,000	31,142,000	31,736,000	30,341,000	30,225,000	29,523,000
National Institute of General Medical Sciences.	1,352,000	1,443,000	2,692,000	2,700,000	2,700,000	2,700,000	2,700,000
National Institute of Child Health and Human Development......	4,534,000	4,249,000	4,614,000	4,800,000	4,600,000	4,600,000	4,600,000
Division of Research Resources........	10,467,000	10,473,000	12,026,000	12,234,000	11,708,000	11,708,000	10,653,000
Total, NIH....	123,986,000	161,006,000	188,210,000	201,612,000	194,390,000	185,874,000	180,726,000

NATIONAL INSTITUTES OF HEALTH

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

DIGESTIVE DISEASES

Digestive diseases such as peptic ulcers, gallstones, and liver disorders are a major health problem in the United States today. Twenty million Americans are treated for some type of chronic digestive disease each year, and according to the National Digestive Diseases Advisory Board, almost half the U.S. population suffers a digestive problem at some time.

Over the last 35 years, however, the efforts of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) to increase the understanding of digestive diseases have contributed to better diagnosis, treatment, and prevention of these health problems.

For example, in 1960, over 3,000 Americans died from inflammatory bowel disease (IBD), primarily Crohn's disease and ulcerative colitis. By 1980, that figure had dropped to well below 800.

The development in the 1970's of new drugs such as cimetidine, ranitidine, and sucralfate has dramatically improved the outlook for people with peptic ulcers. In fact, according to the National Center for Health Statistics, the number of peptic ulcer patients requiring hospitalization for treatment of their condition dropped 43 percent between 1970 and 1980.

New Digestive Disease Centers

NIADDK has recently established 10 digestive disease research centers to enhance the effectiveness of groups of research scientists who study digestive diseases and disorders. There are now 13 federally supported centers across the United States devoted to the study of diseases of the digestive system. Each of these centers brings together both basic scientists, such as immunologists and biochemists, and clinicians, such as surgeons, endoscopists, and radiologists. The centers make possible cooperative research among these investigators by making centralized resources available for research projects and by encouraging new investigations and collaborations in the area of digestive diseases.

Three of the centers are devoted to the study of liver and biliary tract diseases. The center at Yale University in New Haven, Connecticut, is under the direction of Dr. James Boyer and is devoted to the study of liver structure, function, and disease. This center studies: liver transport function and bile formation; bilirubin metabolism and the effects of alcohol; mechanisms of liver fibrogenesis (growth of fibrous tissue in the liver commonly caused by cirrhosis and other disorders); blood flow to the liver and other digestive organs; and the evolution of chronic liver disease treatments, including liver transplantation.

Dr. Joseph Bloomer directs the liver center at the University of Minnesota at St. Paul. Research at this center is focused in three areas: abnormal liver metabolism due to both inherited and acquired liver disorders; liver damage due to viral hepatitis; and liver transplantation.

Dr. Francis Simon directs the hepatobiliary research center at the University of Colorado at Denver where researchers are studying: bile secretion disorders, which may be involved in drug toxicity, cholesterol gallstone disease, and jaundice; disorders of liver lipid metabolism, which may cause cholesterol gallstones and atherosclerosis; and liver cell injury caused by hepatitis B, drugs, metals, and liver cancer.

The center at the New England Medical Center in Boston is under the direction of Dr. Mark Donowitz, and is involved in studying 1) the processes by which materials are absorbed into and secreted out of the body through the gastrointestinal tract; and 2) the diseases that can arise from abnormalities in these processes, especially diarrhea, malabsorption syndromes, and jaundice.

Dr. Don Powell is director of the center at the University of North Carolina at Chapel Hill. Scientists there are focusing their research on diarrhea, irritable bowel syndrome, and IBD. A unique aspect of this center is its collaboration with North Carolina State University's School of Veterinary Medicine, where animal models for the study of these diseases may be developed.

Dr. William Snape directs the new center at the Harbor-UCLA Medical Center in Torrance, California, which is devoted to the study of IBD. Two areas of research emphasis are: examining the immunologic responses of IBD patients and mapping genetic abnormalities that may determine a person's predisposition for IBD.

Research at the center located at the Mayo Clinic and Foundation in Rochester, Minnesota, is under the direction of Dr. Sidney Phillips and is focused on the control of several functions of the digestive tract, including digestion, absorption, and motility. Investigators at this center are studying common diseases such as non-ulcer dyspepsia, functional diarrhea, irritable bowel syndrome, and constipation, that result when these functions are disturbed.

Dr. Tadataka Yamada directs the research center at the University of Michigan at Ann Arbor. Scientists there are studying gastrointestinal peptide hormones, which are involved in appetite regulation, digestion, motility, secretion, and nutrient absorption. This work may help researchers better understand the role of gut hormones in the development of a wide range of illnesses, such as obesity, peptic ulcer, irritable bowel syndrome, and diarrhea.

Dr. James Christensen oversees the activities of the center located at the University of Iowa in Iowa City. Their investigations are focused on the mechanisms of gastrointestinal motility, absorption and transport processes, and the neuroanatomy of the digestive tract. One group of scientists is examining the effects of exercise on motility in the digestive tract. This work may help to explain why long distance runners and other participants in intense exercise often experience nausea, abdominal cramps, and sometimes bloody diarrhea.

Dr. William Silen, using the shared facilities of Harvard University, Beth Israel Hospital, and Brigham and Women's Hospital in Boston, leads a group of investigators studying the structure and function of the smooth muscle and the epithelium throughout the digestive tract. This research may lead to a better understanding of various digestive tract processes, such as the defense mechanisms that protect the stomach and duodenum against injury from gastric acid secretions.

Gallstones

An estimated 25 million Americans suffer from gallstone disease, a problem that costs $1 billion in surgical expenses annually. About 1 million new cases of gallstones are discovered each year.

New Method for Dissolving Gallstones Is Under Study

Dr. Johnson Thistle, an NIADDK grantee at the Mayo Foundation, has successfully dissolved gallstones in patients with a new nonsurgical procedure that uses a solvent called methyl tertiary butyl ether (MTBE). The technique, performed under local anesthesia, involves the placement of a catheter (a very thin, flexible tube) through the abdomen into the gallbladder. Small amounts of MTBE were then injected through the catheter directly into the gallbladder. A constant flushing of fresh solvent was continued throughout the procedure. Within hours the stones in each of the patients had begun to dissolve. If further research proves this technique to be a viable alternative to abdominal surgery for removing gallstones, it will provide not only enormous cost savings but also a safer procedure, especially for those patients at high risk.

Liver Diseases

The liver performs many complex biochemical tasks. As the largest internal organ in the human body, the liver functions as a "chemical factory." It purifies and detoxifies blood, stores certain nutrients, produces a variety of blood proteins, and secretes fluids such as bile that aid in digestion and waste removal. The liver is particularly vulnerable to many types of disease, and each year over 25,000 Americans die from chronic liver disorders.

New Drugs Available for Treating Familial Hypercholesterolemia

Using a combination of two drugs, NIADDK grantee Dr. Scott Grundy at the University of Texas Health Science Center in Dallas has significantly lowered blood cholesterol levels in patients with familial hypercholesterolemia. This disease is marked by extremely high levels of cholesterol in the bloodstream, which may lead to an early death from heart attack. The disorder is caused by a genetic defect that reduces the liver's ability to remove cholesterol from the bloodstream.

Dr. Grundy first gave his patients mevinolin, a drug that inhibits the liver's own production of cholesterol. As a result, the liver activated more of its cell receptors that are specially designed to take up cholesterol from the blood. The uptake of blood cholesterol by these receptors not only replenished the liver's supply of cholesterol but also reduced blood cholesterol levels by about 30 percent. Blood cholesterol levels were further reduced by administering a drug called compactin, which acts to remove bile acids--materials produced from liver cholesterol. The liver's need to replace the depleted supply of bile acids further increased its uptake of blood cholesterol, resulting in an overall 50 percent drop in blood cholesterol levels. This new treatment holds great promise for patients with familial hypercholesterolemia.

Evidence of Non-A, Non-B Hepatitis Virus Found

NIADDK intramural scientist Dr. William Coleman, Jr., and his colleagues at the Food and Drug Administration and the University of Goteborg in Sweden reported a significant breakthrough in hepatitis research with the identification of an enzyme that is involved in the proliferation of the virus believed to cause non-A, non-B hepatitis. Because screening tests for type B hepatitis have almost eliminated the transmission of this disease by blood transfusion, non-A, non-B hepatitis has become the most common form of hepatitis transmitted through blood transfusions.

About 580,000 cases of hepatitis occur in the United States each year, of which 120,000 are believed to be non-A, non-B hepatitis. The identification of markers of this virus is important because it may lead to the development of a screening test to detect the non-A, non-B virus in blood bank supplies and may someday lead to a vaccine to prevent the disease.

Inflammatory Bowel Disease

Both Crohn's disease and ulcerative colitis are chronic inflammatory disorders of unknown cause that affect the intestinal tract and can result in diarrhea, abdominal pain, blood in the stool, and fever. An estimated 2 million Americans suffer from one or the other of these inflammatory bowel diseases. Although certain drugs can control the symptoms of Crohn's disease and ulcerative colitis, there is no known cure for either of them.

Scientists are studying naturally occurring materials that may affect inflammation in the bowel. Certain compounds related to prostaglandins (a group of naturally occurring fatty acids) are known to have an effect on inflammation in various parts of the body. Researchers at several NIADDK-supported institutions, including the newly funded IBD center at Harbor-UCLA Medical Center in Torrance, California, are examining the possible role of these compounds in the inflammation that occurs in IBD.

Mucous Defect Found in Ulcerative Colitis Patients

Drs. Kurt Isselbacher and Daniel Podolsky, NIADDK grantees at Massachusetts General Hospital in Boston, have found that when compared both to Crohn's disease patients and to healthy individuals they weren't patients used as controls, patients with ulcerative colitis have a genetically altered form of mucin, a component of the mucus normally found in the lining of the intestinal tract. The investigators will try to determine if this genetic-based difference plays a role in the onset of ulcerative colitis.

Acute Mesenteric Ischemia

Acute mesenteric ischemia (AMI) is a common condition that occurs when a blood vessel becomes blocked, cutting off the supply of blood to a section of the intestinal tract. This can lead to irreversible intestinal tissue damage and possible infection caused by the spread of bacteria into the wall of the diseased intestines. It is difficult to detect AMI between the time of blockage and subsequent tissue damage without subjecting patients to expensive, time-consuming, and occasionally dangerous examinations.

New Test Developed For Diagnosing AMI

Dr. Gregory Bulkley, an NIADDK grantee at The Johns Hopkins University in Baltimore, Maryland has used animal models to develop a new technique for detecting AMI at its early stages when tissue damage is still reversible.

The technique involves injecting into the abdominal cavity, a solution containing small amounts of radioactive xenon gas, which emits gamma rays. Once in the abdomen, the xenon is absorbed into the intestines. If blood flow is normal, the xenon is rapidly cleared by the bloodstream and carried to the lungs where it is exhaled. However, in tissue where blood vessel blockage has occurred, the xenon remains trapped. After the xenon has been injected, images of the intestinal tract are made with a camera that picks up gamma rays. These images will show any trapped pockets of xenon that may have formed, thus pinpointing the location of possible blockages. The development of this test is important because it holds great promise as a safe and effective means for early detection of AMI in humans.

Diarrheal Diseases

Diarrhea is not only a major health problem but also a major cause of disability in the United States. At best, diarrhea can be distressing, but in more serious cases it can be debilitating and even life-threatening, especially in children, when it leads to dehydration and chemical imbalances in the blood of electrolytes such as sodium and potassium.

Somatostatin: Potential Treatment of Diarrheal Syndromes

Unfortunately, it is not always possible to determine the cause of diarrheal conditions. In such cases, therapy usually involves treating the diarrhea itself. The most effective drugs currently used for treating diarrhea are derivatives of opium, such as paregoric. However, in some people these drugs may have serious side effects on the central nervous system.

Somatostatin is a naturally occurring substance in the body that exhibits several antidiarrheal effects. Previous research has shown that somatostatin given to rats stimulates sodium and chloride absorption and inhibits water and electrolyte secretions in the animals' intestinal tract. The substance also has been shown to decrease intestinal motility and to inhibit the release of hormones that may stimulate diarrhea.

Because somatostatin affects many organ systems throughout the body, NIADDK grantee Dr. Kiertisin Dharmsathaphorn at the University of California at San Diego has developed several variations of somatostatin that specifically act on the digestive tract. Results from this research may lead to an effective treatment for diarrhea.

National Cancer Institute

An estimated 59,900 Americans will die of cancers of the colon and rectum in 1985, making this the second leading cause of death from cancer.

Dr. Paul H. Sugarbaker, an intramural scientist of the National Cancer Institute (NCI), has been studying the survival outcome of patients who had surgery to remove colorectal metastases in the liver. This experience has shown that approximately 30 percent of patients who have had liver resections (removal of part of the liver) are alive and free of cancer 5 years later. This new surgical approach to the treatment of metastatic cancer has also been shown to be successful for the removal of sarcoma cancers derived from supportive or connective tissues) metastases to the lungs.

Research efforts are being directed toward improving the results of this treatment by delivering chemotherapy directly to the tumor site. If cancer comes back after liver resection, 80 percent of the patients experience recurrences within the liver. The current approach, used at NIH, the University of Michigan, and the University of Alabama, is to inject chemotherapy directly into the major artery or vein that supplies the liver. Alternatively, a standard cancer drug 5-fluorouracil (5-FU) can be given into the intraperitoneal cavity by a dialysis catheter. This local-regional chemotherapy maximizes the dose of the drug to the organ at high risk for recurrent disease, the liver, and minimizes toxic side effects for the rest of the body.

NCI grantee Dr. Stanley E. Order and colleagues at The Johns Hopkins University, under a research grant from NCI, has developed the first effective treatment for primary liver cancer using radioactive antibodies to attack cancer cells. This therapy has tripled the average remission time and dramatically reduced the size of these cancers.

In 104 patients with liver cancer, almost half have gone into remission and approximately 7 percent are in total remission. The usual remission rate is 15 percent, and patients survive an average of 3 to 4 months after the standard treatments begin.

With the new therapy, one patient has lived free of cancer for almost 4 years. In another case, a 15-pound tumor was reduced to two pounds after a year's treatment, Dr. Order reported. Patients are given irradiation and two injections of antibodies containing radioactive iodine. The antibodies seek out antigens, or proteins, on the surface of the cancer cells and begin to destroy the liver cancer cells.

Surgery with combined radiation is the standard form of therapy for colon cancer. New chemotherapeutic approaches are being studied under NCI-supported funding at the Mayo Clinic by Dr. Charles G. Moertel. He is investigating whether vitamin C does in fact cure cancer, a popular theory advanced by Nobel Prize Winner Linus Pauling.

Vitamin C was given to 50 patients with an advanced form of colon cancer who had not received prior chemotherapy. Another 50 patients were given sugar pills. Dr. Moertel found that vitamin C therapy was no more effective than the placebo therapy for improving either the interval between the beginning of treatment and disease progression or patient survival. On the basis of this and a previously funded study, high-dose vitamin C therapy was found ineffective against cancer.

Dr. Moertel and colleagues are also part of a NCI-funded cooperative treatment program called the North Central Cancer Treatment Group. They have been studying the efficacy of adjuvant chemotherapy after surgery for colon cancer that had spread to the liver.

Twenty six patients were given 5-fluorouracil following surgery to the colon and liver to see if the drug increased patient survival. The researchers found that patients receiving 5-fluorouracil did not live any longer than those patients who had surgery alone.

Photodynamic therapy with hematoporphyrins is a new treatment technique for a variety of gastrointestinal cancers being developed by Dr. Thomas J. Dougherty at the Roswell Park Memorial Institute in Buffalo, New York.

In the latest animal experiments, a certain wavelength of light was delivered to the tumor site. The treatment destroyed the tumor without injuring normal surrounding tissue. Additional work is now under way to test appropriate energy doses.

National Institute of Dental Research

Salivary glands are an integral part of the digestive system because they secrete certain enzymes, which initiate the breakdown of complex sugars, proteins, and other macromolecules. Salivary glands also secrete immunoglobulins, which protect against infection. Furthermore, by lubricating oral ~~tissues~~ and coating food into a bolus to be transferred to the pharynx, saliva plays a key role in the initiation of swallowing. NIDR research in digestive diseases includes investigations into the functional development and regulation of salivary glands, the composition of saliva, and salivary gland secretions under normal conditions and in certain disease states such as cystic fibrosis and the sicca syndrome (Sjogren's syndrome)--an autoimmune disorder whose symptoms include dry mouth and dry eyes.

Xerostomia, or dry mouth, is an area of particular concern to NIDR because a significant decrease in salivary flow or alteration in the composition of saliva can affect both oral and dental health and nutritional status. Dry mouth is a symptom of certain disorders such as the sicca syndrome and is also a common side effect of over-the-counter and prescription drugs and of radiation therapy. The most common manifestations of dry mouth are an increase in dental caries, gingivitis, and mucosal lesions. NIDR intramural researchers Drs. Phillip Fox and Bruce Baum are studying the functions of salivary glands during normal aging and in individuals with abnormal oral function due to disease or therapeutic procedures. Through studies in their Dry Mouth Evaluation Clinic, these investigators have developed a treatment protocol that has been successful in selected patients with dry mouth.

The drug pilocarpine induces saliva production in patients with salivary glands that are capable of functioning but that do not produce enough saliva. In addition, Drs. Fox and Bam are studying the effect of diminished saliva on swallowing, together with NIH Clinical Center colleague Dr. Barbara Sonies. They have used ultrasonic imaging to help them understand the mechanisms involved in swallowing disorders.

In another NIDR investigation, Dr. James M. Weiffenbach is investigating the ways in which people experience and perceive taste. Dr. Weiffenbach is currently studying how taste perception varies during the process of aging in humans. He and his colleagues are also evaluating the purported role of saliva in taste. Their work shows that saliva is not required for the maintenance of taste buds, but rather to dissolve foods and deliver tastants to the taste buds. Investigators are also evaluating oral sensory disturbances that occur in connection with disease, salivary gland dysfunction, or as an isolated complaint.

National Institute of Allergy and Infectious Diseases

Infectious diarrhea is a significant health problem in much of the world, particularly among infants. Diarrheal diseases such as dysentery, typhoid fever, cholera, and rotavirus infection are especially prevalent in developing countries. Research supported by the National Institute of Allergy and Infectious Diseases (NIAID) has contributed to our knowledge about infectious agents involved in diarrheal diseases and to the development of experimental vaccines against them.

Cholera is perhaps the most important cause of death from diarrheal disease because of the severe watery diarrhea produced by various strains of the bacterium Vibriocholerae. Several cholera vaccines have been under development but they have not proven effective over long periods of time and they have been associated with adverse effects due to cholera toxins contained in the vaccine.

Using recombinant DNA techniques, scientists have produced vaccines that retained the ability to protect against cholera while excluding components known to produce toxins. These newly developed oral cholera vaccines have been tested in volunteers by Dr. Myron M. Levine, Director of the Center for Vaccine Development supported by an NIAID contract at the University of Maryland in Baltimore. The vaccines are administered by mouth to achieve immunity in the gastrointestinal tract, where the bacteria take hold. Immunized volunteers were subsequently challenged with a strain of cholera. They were protected against infection, but a previously unrecognized toxin present in the vaccines was found to cause minor diarrhea. Field trials in Kenya using an oral vaccine are in the planning stages, but meanwhile Dr. Levine is continuing to test experimental vaccines that may prove to be free of the newly identified cholera toxin.

Diarrhea is a leading cause of illness and death among children under 5 years of age in many parts of the world. Infants hospitalized with acute diarrhea are generally treated with oral rehydration solutions to provide necessary fluid and to maintain electrolyte balance. Oral rehydration solutions recommended for use by the World Health Organization contain glucose, sodium, and a base of bicarbonate or citrate. Food is not usually given for 24 to 48 hours, in the belief that it might aggravate the diarrhea.

This regimen was recently challenged in an NIAID-supported study conducted by Dr. Mathuram Santosham of The Johns Hopkins University School of Medicine, and his colleagues at the Indian Health Service Hospital in Whiteriver, Arizona. Dr. Santosham gave babies with diarrhea a soy-based lactose-free formula after just 4 hours of oral rehydration therapy. He found that thes babies had a greater than 50 percent reduction in stool output and a 40 percent shorter duration of illness compared to those receiving standard therapy.

In addition to improving the course of acute illness, nutrients provided by the formula would be especially important for undernourished infants or those in developing countries who may have diarrhea several times a year. Babies who are breastfed should continue to receive breast milk when they have diarrhea.

A less severe but common problem for adults is travelers' diarrhea, the most frequently encountered health problem among the estimated 8 million U.S. residents who travel each year to developing nations. Together with the NIH Office of Medical Applications of Research, the NIAID held a consensus conference in January 1985 on travelers' diarrhea. The consensus panel, chaired by Dr. Sherwood Gorbach of Tufts University in Boston, Massachusetts, considered whether travelers to developing countries should take antimicrobial drugs to prevent diarrhea.

Although diarrhea may sometimes be difficult for the traveler to avoid, the panel underscored the importance of avoiding potentially contaminated food and water--raw vegetables, raw meat, raw seafood, ice, unpasteurized milk--and recommended drinking bottled carbonated beverages and hot tea or coffee.

The panel also recommended that medications be obtained from a physician before traveling but used only when symptoms occur. In many cases, antidiarrheal compounds such as Lomotil or Pepto Bismol can provide fast relief. For more severe cases, antimicrobial drugs such as trimethoprim or doxycycline can be taken symptomatically to limit diarrheal illness to 1 or 2 days.

Travelers' diarrhea can be caused by many organisms, and one that is receiving increasing study is a parasite called *Giardia lamblia*. *Giardia* has also caused diarrheal disease in children who have attended day care centers and in people who have drunk contaminated water in the remote wilderness of Canada and the western United States.

NIAID scientists led by Dr. Theodore E. Nash are seeking to understand why some people infected with *Giardia* do not develop symptoms whereas others develop severe diarrhea and malabsorption. In addition, it would be important to know whether the same strains of *Giardia* can infect humans as well as other mammals, since it is thought that beavers are responsible for mountain lake and stream contamination.

Dr. Nash and his colleagues have used recombinant DNA technology to develop a test that enables them to recognize differences among various strains of *Giardia*. This technique will enable scientists to distinguish a nonepidemic strain from one that causes disease. Among the isolates studied to date, Dr. Nash has not found a species that appears to be unique to humans compared with other mammals.

National Institute of General Medical Sciences

The National Institute of General Medical Sciences (NIGMS) supports basic research and research training that provide the foundation for a better understanding of fundamental life processes. This research supplies new knowledge, theories, and concepts for the disease-targeted programs of other NIH institutes.

NIGMS research programs encompass cellular and molecular biology, genetics, pharmacological sciences, and biophysics and physiological sciences. The Institute's Pharmacological Sciences Program supports research concerned with the cytochrome P-450 enzyme system of the liver--a system that is particularly important in drug metabolism since it helps transform foreign substances to less toxic compounds.

NIGMS grantee Dr. Curtis Omiecinski at the University of Washington, Seattle, is studying cytochrome P-450 genes. He is investigating how the genes for two cytochromes P-450 are expressed in rats and rabbits and how gene expression may change as the animal grows.

He has developed a highly sensitive method for detecting individual levels of the mRNA's (messenger RNA's--molecules that transmit genetic information from the cell nucleus to the cytoplasm, where protein synthesis takes place) for two cytochrome P-450 enzymes produced by the liver of an animal treated with phenobarbital. In the past it has not been possible to discriminate between these individual mRNA's or the genes for these two enzymes.

Using his new detection methods, Dr. Omiecinski has demonstrated that the livers of adult rats who have not been treated with phenobarbital contain very little or no detectable mRNA for either enzyme. In the lives of rats pretreated with phenobarbital, levels of these mRNA's rise dramatically. This indicates that the animals develop the biochemical means to metabolize doses of the drug after they are exposed to it.

In developmental studies, Dr. Omiecinski discovered that developing rat embryos do not have the ability to synthesize the enzymes in response to phenobarbital. They acquire this ability at birth and it remains through adulthood. These studies provide a means for examining the susceptibility of animals to toxic effects of chemicals and extend our knowledge of liver function.

Acetaminophen (the active ingredient in many nonaspirin-containing pain relievers, such as Tylenol®) is generally regarded as safe in normal doses. However, if taken in excessive quantities, acetaminophen causes severe damage to the liver. NIGMS grantee Dr. Steven Cohen at the University of Connecticut, Storrs, is working learning more about the mechanisms by which acetaminophen causes liver cells to be destroyed.

By studying the livers of mice, as well as cultured mouse liver cells, Dr. Cohen has identified the endoplasmic reticulum (a cellular organelle that is involved in the storage, segregation, and transport of proteins manufactured by the cell) as the site of initial attack by the drug's metabolites (byproducts of metabolism).

These studies are among the first to identify subcellular sites of acetaminophen-induced biochemical alteration. Thus, they are a crucial first step in understanding acetaminophen toxicity in the liver and may eventually contribute to improving the drug and treating individuals who have taken overdoses.

National Institute of Child Health and Human Development

In its study of digestive conditions in infancy and early childhood, the National Institute of Child Health and Human Development (NICHD) places particular emphasis on the study of human breast milk. A coordinated research grant and contract program has been established to expand knowledge of the detailed composition and function of the many constituents of human milk and its importance in the development of normal and high-risk infants. As a result, this unique biological fluid is now recognized as a valuable source of nutrients, growth factors, and antimicrobial agents for newborn infants, particularly those of low birth weight. Other NICHD research priorities in the area of infant nutrition are discussed in the separate report on maternal and child health.

Discoveries continue to be made about the biochemistry of human milk. One milk enzyme, lipase, digests lipids (fats). NICHD grantee Dr. Margit Hamosh and her colleagues at Georgetown University in Washington, D.C., have discovered that lipases from a normal infant's mouth and intestines work together with milk-derived lipases to digest the lipids contained in milk and to attack the lipid surfaces of various intestinal parasites.

Studies of the mammary gland's role in the immune system have led to exciting information about the distribution, origin, and function of different cellular and soluble components of breast milk and how they affect the newborn's immune function.

In one study of almost 200 infants, NICHD grantee Dr. Pearay Ogra at Children's Hospital in Buffalo, New York, found that both breast-fed and bottle-fed infants who developed diarrhea showed similar recovery rates of the rotavirus from fecal specimens during a seasonal period of rotavirus infection. However, severe diarrhea was significantly more common among infants who were wholly or partly bottle fed. Bifidobacterial (normal bacteria in the intestine) growth, which appears to combat diarrhea, was much greater among breast-fed babies. The investigators suggest that breast milk may induce beneficial changes in the intestinal bacterial flora.

Researchers are investigating the mechanisms by which immunologic characteristics are transmitted from mother to infant via breast milk. Progress in this area has been made by NICHD grantee Dr. Leonard Seelig at the University of Texas in Dallas. Studies in rats have shown that immunologically active T-cells (lymphocytes) travel to the mammary gland during lactation and infiltrate the breast milk. When breast milk is ingested, some of the mother's lymphocytes contained in the milk travel through the infant's gastric membrane and become established in neonatal tissues. Further study will try to determine if these cells are also absorbed through the infant's intestinal wall. An increased understanding of how the mother's lymphocytes, conveyed through milk, "seed" the infant's lymphoid tissue could provide a new means of controlling and preventing disease during the newborn period.

Other investigations focus on colostrum, the first milk produced by the nursing mother, to determine what effects colostrum's antibodies, antigens, and possible immune complexes have on the nursing newborn. Because the newborn's gastrointestinal tract is underdeveloped, immune substances may pass through it into the circulation, providing systemic immunity. Colostrum also affects maturation of the intestinal tract and the development of gastrointestinal defense mechanisms, which appear to be stronger in breast-fed babies. NICHD-supported researchers led by Dr. W. Allan Walker at Massachusetts General Hospital have determined that oral human immune substances can be safely given to infants and provide protection throughout the gastrointestinal tract. These findings will be valuable in the treatment of premature or very ill infants unable to breast feed.

Malabsorption syndromes and food intolerances are responsible for a great deal of infant sickness. To understand the causes of such problems, grantee Dr. Marian R. Neutra at Harvard University, is conducting studies to elucidate the function of cellular systems that are responsible for transporting large molecules through the lining of the small intestine. She has shown that these processes are associated with specialized cells in the different layers of the intestinal wall and are selective as to the types of molecules transported.

Infant colic is one of the most common problems encountered in pediatric practice today. Under a Small Business Innovative Research grant, Judith A. Bunge, affiliated with Sweet Dreems, Inc., in Westerville, Ohio, is developing a technique that uses motion to soothe colicky infants. In the first phase of the project, a clinical trial confirmed that a gentle vibrating device attached to an infant's bed reduced colicky episodes. The project, now in its second year, has the potential to produce a device that will be safe and effective in reducing colic.

Division of Research Resources

The recent discovery of a monkey model for both colon cancer and colitis is enabling scientists to explore possible causes of these poorly understood disorders and to develop new treatments.

This discovery was made by scientists at the Oak Ridge Associated Universities Marmoset Research Center in Tennessee who noticed an unusually high incidence of colon cancer and chronic colitis among cotton-top tamarins, small nonhuman primates native to South America. Shortly after this discovery was published, investigators at the New England Regional Primate Research Center (NERPRC) in Southboro, Massachusetts, confirmed the association of colon cancer and colitis in the cotton-top tamarin.

The NERPRC is one of the seven regional primate research centers (PRC's) supported by the Animal Resources Program (ARP) of the Division of Research Resources (DRR). The ARP helps meet the need of researchers for high quality, healthy animals and specialized animal research facilities.

The cotton-top tamarin is a convenient animal to study because of its naturally short generation span. Also, colitis and colon cancer produce similar tissue changes in the tamarin and the human. The animal model is unique, according to Laura V. Chalifoux of the NERPRC, because colon cancer develops following colitis in these animals as it often does in humans.

Several collaborative studies that explore potential causes of colitis and colon cancer are under way at both the NERPRC and the Oak Ridge facility. Scientists are examining the microflora present in the bowel of the cotton-top tamarin to determine if a microbe might cause colitis in this species. The expression of certain genes suspected of causing cancer is also being examined in this primate, as well as immunological changes associated with either colitis or colon cancer. Genetic records and breeding manipulations are being used to determine the role genetics might play in predisposing an animal to colon cancer.

Researchers collaborating with either the Oak Ridge center or the New England center are also testing various anti-inflammatory drugs on cotton-tops with colitis to determine if they can lessen the symptoms of the disease. This animal model allows drugs to be screened for effectiveness and side effects before these medications are administered to humans.

Because the cotton-top tamarin is an endangered species, its availability is limited, as are the kinds of studies that can be done on the animal; however, a variety of nonlife-threatening techniques, including x-rays, biopsies, and blood sampling, allow information to be gathered without endangering these animals.

Rather than reducing the number of these animals, biomedical research has had the opposite effect. The population of cotton-tops is dwindling dangerously in its native habitat of Colombia, but colonies of the monkey are breeding well at several primate centers and universities.

The study of colon cancer at the cellular level has also produced significant results. With funding from the National Cancer Institute and DRR's Biomedical Research Support (BRS) program, investigators led by Dr. Michael Brattain at Baylor College of Medicine in Houston, Texas, have discovered that colon cancer cultures secrete a compound that stimulates cell growth.

Crude extracts containing this compound stimulated the growth of normal mouse embryo cells in the laboratory. When the scientists purified these extracts, they were able to isolate both a transforming growth factor (TGF) and a tumor inhibitory factor (TIF). The TGF stimulated the growth of two of five human colon cancer cell lines. The TIF isolate, in contrast, inhibited the growth of the same cancer lines. TIF also inhibited the growth of an additional colon cancer line and one type of cultured skin cancer. Adequate quantities of TIF could completely stop the growth of all four cancer cell lines. TIF inhibited the growth of these tumor cells in a nontoxic way. It didn't kill the cells but, instead, induced them to differentiate to a greater degree.

Outlook

In addition to the research described in this report, NIH conducts and supports research on many other digestive diseases such as pancreatitis, esophagitis, malabsorption syndromes, liver cirrhosis, diverticulitis, and anorectal diseases. The known causes of digestive diseases range from infections, metabolic disorders, or genetic defects to neuromuscular disorders, toxins, and reactions to stress. As a result of the NIH's intramural research program and the awarding of extramural grants to scientists at universities and medical centers around the country, exciting new advances in digestive disease research continue to be made.

DRUG ABUSE

Obligations

	1984 Actual	1985 Actual	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	1987 Estimate
Public Health Service:						
Health Resources & Services Administration:						
Bureau of Health Professions						
Area Health Education Centers....................	$140,175	$64,970	$64,970	$62,176	---	---
Physician Assistants................	3,500	3,100	3,100	2,967	---	---
Family Medicine Residencies................	---	17,010	17,010	16,279	$5,613	---
General Internal Medicine and Pediatric Residencies...............	---	3,216	3,216	3,078	1,000	---
Alcohol, Drug Abuse, and Mental Health Administration:	71,098,000	80,576,000	91,807,000	87,859,000	80,488,000	90,548,000 1/
TOTAL......................	$71,241,675	$80,664,296	$91,895,296	$87,943,500	$80,494,613	$90,548,000

1/ $7,605,000 is to be provided to ADM Drug Abuse obligations from OASH reimbursements for AIDS projects.

FOREWORD

The number of Americans using illicit drugs increased dramatically in the two decades from 1960 to 1979. This upward trend was halted, or even reversed, for many drugs between 1979 and 1984. However, our most recent evidence, from a study of drug use by high school seniors, shows that the downward movement has ceased. Of particular concern has been the continued increase in the use of cocaine. Results from NIDA's Monitoring the Future project at the University of Michigan indicate that cocaine use by the class of 1985 is more frequent than in 1984 among virtually all of the subgroups that were examined, including both males and females, college-bound and non-college bound, rural and urban areas, and all regions of the country except the south. Futhermore, between 1981 and 1984, there has been a threefold increase in the number of emergency room mentions of cocaine and in medical examiner reports of cocaine-related deaths. More recently, the intravenous use of illicit drugs has been identified as a major factor in the transmission of Acquired Immunodeficiency Syndrome (AIDS).

It is also disturbing that since 1975 the average age of first use of psychoactive substances has been decreasing. Early initiation into drug use has been found to significantly increase the risk of serious adverse health consequences. On average young people first experiment with the "gateway" drugs--alcohol, tobacco, and marihuana, during the junior high school years. The population susceptible to drug use is far from homogenous. There are age, race, social, and geographic differences in drug use, but no one group has been found to have immunity. Accordingly, efforts to reduce drug abuse must be varied and multifaceted to address diverse target groups. Because of the heterogeneity of the population susceptible to drug abuse, classification schemes are helpful in targeting efforts to specific subgroups. One model which is useful in elucidating NIDA's strategy divides the susceptible population into three target groups:

- Non-users and early experimenters. Primary prevention is useful here.

- Casual or social users. Secondary prevention or treatment is emphasized here.

- Chemically dependent, compulsive, or addicted users. The emphasis for this group is on tertiary prevention, treatment, and rehabilitation. For some, efforts may need to include the means to motivate the drug user to seek treatment.

Non-Users and Early Experimenters

The earlier drugs are first used and a pattern of use established, the more likely it is that dependency and other serious adverse consequences will result. Further, the early use of alcohol and tobacco may lead to use of marihuana which in turn may lead to later cocaine and heroin use (gateway effect). One working hypothesis, for which additional research is required, is that by delaying the age at which an individual first uses alcohol, tobacco, or marihuana, we may reduce the number of persons who go on to use illicit drugs, or reduce the severity of their eventual drug realted problems. Accordingly, efforts aimed at preventing drug use by children and adolescents, through decreasing the influence of peer pressure and altering the atmosphere supporting risk-taking behavior, are of crucial importance.

Casual Users

The group of so-called "recreational" or occasional users constitutes another group on which we must focus demand reduction efforts for a number of reasons. First, they use and abuse a large amount of drugs and thereby contribute to a demand which fuels the supply side chain of drug production and distribution. Second, these users frequently show few if any adverse consequences and seem to be enjoying the effects of drug taking. Casual users are also likely to initiate others into drug use and to support continued drug use by the establishment of social norms. Third, since the use of addictive drugs may increase with time, many casual users progress from occasional to regular use and some to compulsive use. Fourth, efforts directed at casual users are particularly important because many of these users are parents who will shape the attitudes and practices of their children. Societal attitudes about drug use will be most affected by how we approach this group-- whether we ignore their drug use or try to prevent it.

Compulsive Users

Once a pattern of compulsive drug use has become established, it becomes difficult for the user to moderate his drug use. Drug use may continue despite a breakdown in relations with family and friends, economic disaster, encounters with the law, and the development of serious medical and psychological problems. Education efforts aimed at this population are rarely effective. Intervention and treatment offer the only hope for breaking the hold of drugs on this population before the disorder runs its natural course.

To reduce the illicit use of drugs in America, NIDA develops knowledge and disseminates the results of research projects to the scientific and service provider communites, as well as the general public.

Research

Research forms the base on which successful prevention and treatment efforts are built. NIDA stimulates and conducts scientific research in a number of areas which have the potential for increasing our knowledge about how to prevent and treat drug abuse. The research program includes studies to determine drug use patterns and the long-term consequences of drug abuse, the etiology of drug abuse, the effects of drugs on the central nervous system, the biological, psychological, and environmental factors which increase or decrease the likelihood of drug use, the adverse medical consequences of drug use, and the effectiveness of drug abuse prevention and treatment programs. Information gained from this research is disseminated on a timely basis to researchers, medical practitioners, educators, clinicians, State and local officials, and the public. Through prevention research studies, techniques are developed to discourage non-users from initiating use or active users from progressing to more frequent use. Epidemiologic studies of drug use patterns, as well as the studies of the abuse potential of drugs, provide data necessary for other Federal agencies (e.g., the Drug Enforcement Administration, Department of Treasury, and the Food and Drug Administration) to carry out their responsibilities under the law.

Direct Operations

By stimulating and supporting cooperative activities with parents' groups and other private sector and non-Federal organizations, application of these research and prevention findings can discourage drug and alcohol use, especially among school age children and youth. For example, giving leadership and assistance to such groups results in the development of media materials to discourage drug use and provides needed information on the latest and most effective prevention approaches. Data on the etiologic and adverse consequences of drug use, derived from NIDA studies, are a critical element in this effort. NIDA also provides assistance to other Federal agencies, including the White House Drug Abuse Policy Office, the Office of the First Lady, the Drug Enforcement Administration, the Department of State, and ACTION. These Federal departments and agencies rely on NIDA for research data and current information concerning the best drug abuse prevention strategies.

NIDA's role in drug abuse treatment was redefined in Fiscal Year 1982 by the enactment of the Alcohol, Drug Abuse and Mental Health Services Block Grant. Prior to this legislation, NIDA was the primary channel through which Federal support for drug abuse treatment was provided to the States. The Block Grant legislation provides support to the States in a more direct and flexible manner. NIDA has continued, however, to play an important national leadership role in the drug abuse treatment system. A primary goal of our national leadership mission is the dissemination of research findings through written materials, presentations at professional meetings and workshops, and support for State efforts to increase the involvement of the private sector in the development and support of treatment and rehabilitation programs.

EVOLVING STRATEGIES -- SUCCESSES AND GAPS

At one time, Federal efforts to reduce drug use concentrated primarily on the third of the target groups: the compulsive drug abuser - especially opiate addicts. Efforts were focused on inner city, minority populations. From these efforts we learned that drug abuse treatment and rehabilitation could be implemented successfully. More recently, the focus has shifted to the first target group, the non-users or early experimenters, and priority has been placed on primary prevention. There has also been a broadening of the target populations, with more emphasis now placed on techniques, such as media campaigns or school-based efforts, which reach wide sectors of the population at risk of drug abuse. Up to the present time, there has never been a strong Federal effort aimed specifically at casual users.

To respond to the changing nature of the national drug problem, continued strong support of successful programs must now be supplemented by new programs aimed at filling gaps identified in the current national strategy for all three user groups. Particular attention must be directed toward cocaine users and the new user populations who may be different from the traditional opiate addict.

Non-Users and Early Experimentors

Research has provided us with information about the effectiveness of various prevention programs. Especially promising are social resistance approaches that help youth learn skills needed to resist social pressures to use drugs. However, additional research is needed to determine the long term impact of these approaches and to look at their effectiveness with low income and ethnic minority groups. Additional research is also needed to identify other effective prevention approaches, to complement and reinforce the social resistance approaches, and to reach those youth for whom the social resistance approaches are ineffective. An array of effective prevention approaches is needed, focusing not only on peers, but also on the family, the school, the media, and the broader community.

Primary prevention programs targeted to the non-user or early experimenter, such as media campaigns and "Just Say No" Clubs, should be continued and enhanced with other community level efforts. What parents and peers believe, and the messages they and the media convey, make a difference. Societal values and beliefs about drug use are closely related to levels of drug use by adolescents and young adults. Trends in the perceived health, social, and legal risks associated with drug use are inversely correlated with levels of use. Our prevention efforts will focus on studies designed to improve techniques to discourage drug use before it begins.

Casual Users

A sizable percentage of casual users grew up in the 1960s, when illicit drug use was widespread and almost considered normal. These people, the majority of whom are now aged 25-45, have attitudes about drug use shaped by their personal experiences. Many have experimented with, and many continue to use drugs. Some have progressed to regular, compulsive drug use, including use within the workplace, which is a growing concern. Use began when knowledge of the adverse effects of drugs such as marihuana and cocaine were less well known. By appropriately focusing additional knowledge about the health consequences of drug use, including the role of drug abuse in the development and spread of HTLV-III diseases, at this population we may stop or limit use, and prevent progression to more serious use. Casual users also include youth who have progressed beyond experimentation, but have not, as yet, established compulsive drug use patterns. Efforts to address casual users will include demonstration of research principles found to be effective, as well as further clinical studies to develop more effective treatment programs.

Drug detection programs in the workplace may reduce the prevalence of use. Some workplace drug use may cease when it is announced that screening is to be done. Employees whose use has become compulsive will be detected and appropriate intervention should prove beneficial both to drug users and employers. Additional demonstrations are needed, particularly among workers whose positions are critical to the general health and safety of the population, to show that screening programs not only reduce the level of drug use, but also improve performance and are cost-effective. Improved occupational safety will encourage more industries to initiate similar programs.

Clinical studies to develop and evaluate treatment programs specifically directed at adolescent drug users should also be initiated. Adolescent drug use is a significant risk factor in the development of long-term adverse health and social consequences. The majority of past studies of drug treatment have been directed at drug users beyond the teen years, and have only limited use in the development of effective treatment programs for adolescents. Studies of various combinations of therapeutic interventions, in the family, the school, and peer-groups, are needed to find effective ways to treat adolescent drug users.

Compulsive Users

The compulsive, dependent, or addicted user is not likely to be greatly influenced by educational efforts or fear of medical, social, or legal consequences. Drug abuse and the pursuit of drugs have become integral parts of the lifestyles of such abusers. Relationships with conventional society, including family members, non using friends, and the world of work, have become attenuated. In part, this group of compulsive drug abusers is composed of antisocial individuals who steal, deal drugs, or do whatever is necessary to obtain drugs. These abusers, who need intensive help in restructuring their lives, have been found most resistant to treatment. Research is needed to determine why this group resists treatment and to develop effective intervention strategies. As the relationship between intravenous drug use and AIDS is clarified through epidemiologic studies, the need to engage compulsive drug users into treatment programs may become more critical to the general population. Finding effective measures to address compulsive users will focus on treatment interventions directed at specific high-using subgroups. Examples of population-specific programs are:

- Development and evaluations of programs involving the judicial system and aimed at high risk juvenile and adult criminal justice populations may help to identify the role of compulsive drug use in the development of anti-social behavior. By identifying juveniles at high risk for developing anti-social behavior or already exhibiting antisocial behavior and deterring or reducing their drug use, it may be possible to reduce their future drug and alcohol use, as well as their criminal behavior. Demonstrations which monitor parolees by urine screening and other research focused on the high correlation between drug use and crime may result in substantial reductions in criminal behavior and drug use. We must now focus on the nature of the antisocial personality to determine why those who fall into this population are so much more resistant to existing treatments.

- Other compulsive drug abusers are uncomfortable with their addictive lifestyles. They maintain some ties with conventional society. Although these ties may be tenuous, they provide a basis and motivation for behavior change. These abusers have been found more willing than others to enter and remain in treatment and to benefit from the treatment process. Additional research is needed to increase the effectiveness of treatment and followup services with this population.

- The recent increase in cocaine abuse makes it especially important to increase efforts to identify effective treatment approaches for cocaine abusers. Current research in this area is in its early stages, and considerable additional research is needed.

NIDA meets its responsibilities under the Federal Strategy for Drug Abuse by supporting and conducting research to develop more effective prevention and treatment programs. Disseminating this information and stimulating public and private sector education and prevention programs complement our role in reducing the demand for drugs in America.

The following description of NIDA's research and direct operations is intended to provide the reader with a sense of the magnitude of the problem, the complexity of our task, and the breadth of our approach.

OVERVIEW OF RESEARCH PROGRAMS

The National Institute on Drug Abuse (NIDA) supports research projects to measure the nature and extent of drug taking behavior and its consequences; improve our understanding of the the biological and behavioral bases of drug use; and to develop more effective prevention and treatment programs. To accomplish its mission, NIDA research is supported extramurally through grants and contracts and intramurally at the Addiction Research Center (ARC) located in Baltimore, Maryland.

Over the past several years, much has been learned about biological and behavioral factors involved in drug abuse. To appreciate the significance of recent findings about the biological basis of substance abuse behavior, it is helpful to remember that since the 1930's, popular belief about the addictive disorders focused on three often distinct views. One view held that drug abuse reflected a weakness in character at best, and moral turpitude in the extreme. Proponents of such views tended to downplay or ignore another strongly held belief that biologic factors either predisposed individuals to abuse substances or acted as the central cause of such behavior. Later, others concluded that drug abuse was the result of an interaction between physical characteristics and environmental circumstances. As we look back now over 50 years of government sponsored research, the likelihood of achieving significant progress in actually understanding the basis for abusing drugs has never appeared more promising. In the past few years, discoveries of basic biological processes involved in the actions of commonly abused drugs have revolutionized the theoretical and practical approaches to drug abuse prevention and treatment. Not only have opiate receptors been hypothesized and discovered, efforts now to isolate different subtypes responsible for producing different pharmacologic and behavioral effects are well underway. Adding to our understanding of the basic actions of drugs, are recent findings that suggest the reason drugs are habit forming may be related to "reward circuits" in the brain which respond to a variety of drugs in the same rewarding manner. These major accomplishments not only point out new directions for preclinical investigations, but reinforce our belief that significant progress toward reducing the demand for drugs in our society, through knowledge gained from basic research, is an achievable goal.

Important as basic research is to reducing drug abuse in this country, clinical investigation is the vital link between basic and applied studies. It serves as the bridge for translating findings of the basic mechanisms of drug actions into more effective prevention and treatment strategies. Observations made throughout the course of clinical practice also serve to focus further research efforts on the underlying factors involved in drug abuse behavior.

Careful monitoring of the nature and extent of drug abuse and its adverse health consequences is vital to the rational allocation of our limited resources. Epidemiologic studies form a basis for measuring the success of our prevention efforts, and alert us to emerging problems requiring increased attention. Epidemiologic studies can also identify risk factors, and adverse health consequences helpful to understanding the etiology of drug abuse problems and for identifying promising treatment approaches. Drug abuse incidence and prevalence estimates are produced through periodic surveys of high school students and the general population. Complementing national surveys are NIDA programs measuring the nature and extent of the adverse health consequences resulting from drug abuse. These data collection and analysis efforts are an essential feature of NIDA's mission to monitor the magnitude of the problem and warn Americans of the danger drug abuse can pose to their everyday health and safety.

Applied research also provides needed balance to NIDA's mission through translation of research results into more effective prevention and treatment services. Clinical testing of treatment strategies using new pharmacotherapeutic agents, development of intervention approaches using drug detection technology, and prevention programs specifically directed toward adolescents are examples of how application of NIDA research deters or reduces drug abuse behavior.

Clinical research evaluating new treatment strategies has focused not only on primary substance abuse disorders, but on allied problems as well. Recent studies have identified high prevalence rates of psychopathology among opiate addicts, including major depression, anxiety disorders, alcoholism, and antisocial personality. Some of these conditions-- depression and anxiety disorders -- are amenable to treatment with pharmacologic agents. In addition, pharmacologic agents may be used to treat the substance abuse disorder itself. For example, methadone for narcotic detoxification, and naltrexone as an adjunct to the aftercare process. Tricyclic antidepressants have been used to improve retention among opiate addicts in treatment programs, and for treatment of depression which is characteristic of cocaine abusers after their use of cocaine has been discontinued.

Many companies have established employee assistance programs to prevent and intervene in drug abuse in the workplace. Application of basic research findings has led to the growing use of drug detection technology in these programs throughout the private sector. Developed nearly 20 years ago to monitor the drug use of military personnel in Vietnam, techniques to screen body fluids for the presence of drugs has increasingly been applied in industries where public safety can be compromised due to employee drug use.

Because drug abuse has become widespread among younger people over the past decade, efforts to design treatment approaches tailored to the needs of children and their families have intensified. Through NIDA supported research, it has been demonstrated that special attention to the needs of adolescent drug abusers can effectively intervene in troubled families and interrupt the development of more serious substance abuse problems. In one study designed to engage adolescent drug abusers and their families into treatment, it was found that over eight-of-ten families that received intensive outreach services successfully completed family therapy, compared to 35 percent in a control group which did not receive special attention. The same study demonstrated that only 14 percent of the experimental engagement group dropped out of treatment compared to 33 percent of the controls.

PROGRAM DESCRIPTION

The need to present our research program in terms that reflect the breadth and complexity of our task, the progress we have achieved, and our hope to significantly reduce the demand for abuseable substances in our society, prompted development of ten major mission objectives which describe our research programs according to their objectives or functional category. Presenting our research portfolio in this manner promotes a better understanding of our major goals and permits more effective management of resources. The ten major research mission objectives are:

I. To monitor the incidence, prevalence and patterns of drug abuse.

II. To promote an understanding of the risks and adverse health consequences of drug use.

III. To develop more effective prevention programs and foster their utilization.

IV. To develop more effective treatment programs.

V. To promote an understanding of the molecular and cellular actions of abused drugs.

VI. To promote an understanding of the actions of drugs on the central nervous system.

VII. Understanding the behavioral actions of drugs of abuse.

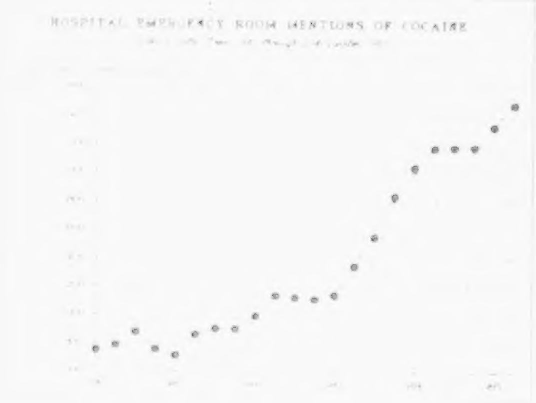
VIII. To promote the study of the chemical composition and structure of abused drugs.

IX. To promote an understanding of the metabolism and distribution of abused drugs.

X. To provide technological services in support of drug abuse research and prevention, and to disseminate the findings of research on the causes, consequences, prevention and treatment of drug abuse problems.

I. MONITORING THE INCIDENCE, PREVALENCE AND PATTERNS OF DRUG ABUSE

One of the basic missions of any public health agency is to determine the nature, extent, and health consequences of the disorder. In the area of drug abuse, this effort assumes an added degree of importance because of fluctuations that occur in both the numbers of people using drugs and the patterns in which drugs are used. For example, the number of people admitted yearly to emergency rooms following cocaine use, as reported to the Drug Abuse Warning Network (DAWN), increased almost 400 percent in the five years between 1980 and 1985. The magnitude of such an increase is rarely found in any other public health area.



For a number of years, the collection of accurate information on the incidence and prevalence of drug use was thought to be difficult if not impossible because of its illicit and stigmatized nature. One of NIDA's major accomplishments in its early years was the development of reliable methods for overcoming these problems. These efforts resulted in what are now our three most important ongoing data collection programs: the Drug Abuse Warning Network (DAWN), the High School Senior Survey, and the National Household Survey. Collectively, these major programs provide us with timely and accurate information on changes in the incidence and prevalence, as well as the adverse health consequences of drug abuse in America.

Despite the progress we have made, there remain important problems in the collection of drug abuse data. For example, we have yet to find satisfactory ways of studying important subgroups, such as high school dropouts or homeless persons, where drug abuse is thought to be more widespread than in the general population. While the effect on yearly national estimates of drug use are only slightly influenced by the underrepresentation of these subgroups, drug use trends are relatively unaffected since the error is assumed to be fairly constant from one year to the next. Nevertheless, data on the drug use patterns of high using subgroups is essential to the development of effective prevention and treatment approaches. There are also limitations in the range of data we collect which prevent us from realizing the maximum potential of these studies in our research program. Furthermore, important problems posed by the costs of these studies limit both the frequency that they can be conducted and the range of data that can be collected. The search for solutions to these issues are now in the forefront of our efforts to monitor drug abuse in the United States.

The National Household Survey has been conducted by NIDA periodically since 1972. Data collection for the most recent survey was conducted in the last half of 1985, and major findings will be available in May, 1986. The current National Survey will make drug abuse prevalence estimates based on some 8,000 interviews, including an oversampling of certain ethnic minorities to insure that drug use among Blacks and Hispanics is accurately reflected in the overall national estimates.

In addition to obtaining the standard measures of drug use prevalence, including alcohol use, the 1985 National Household Survey also collects information on depression and dependency, as well data on health status and perceived risks associated with drug use. Data obtained from the National Household Survey will provide the basis for a significant amount of additional research, the results of which will be used to improve the next survey planned for 1988.

As an example of the measures NIDA has taken to improve its ability to make estimates of the extent of drug use in America, questions were added to an 1985 Gallup Poll which provided information about alcohol, marihuana, and cocaine use. Not only was valuable drug abuse prevalence information gained in this manner, using the Gallup Poll demonstrated that this type of survey method could provide timely assessments of drug use trends in the years between the National Household Surveys. Another methodological study under development will test the feasibility of using telephone surveys to measure drug use, attitudes, and other drug abuse related issues.

Through the Drug Abuse Warning Network, NIDA collects data from hospital emergency rooms and medical examiner offices located in 27 selected major metropolitan areas throughout the United States. To assure that DAWN data are as accurate and methodologically consistent as possible, a number of quality control procedures are used. These include full documentation of all DAWN field procedures, and audits or reabstracting studies of reporting facility records which were initiated as a regular part of DAWN operations. In addition, beginning in 1986, NIDA will begin to implement a sampling plan which will allow DAWN data to be used to make population based estimates for both the nation and selected metropolitan areas.

NIDA continues to support the Community Epidemiology Workgroup (CEWG), which is comprised of state and local epidemiologists who meet semi-annually to report on drug abuse trends in their area. Workgroups within States have already been established New York, New Jersey, Florida, and Louisiana, as those states have made the decision to operate networks similar to the national network within the boundaries of their respective states. The Pan American Health Organization also expressed interest in this concept and conducted a one-day session at the CEWG meeting held in Miami, in December of 1985, on ways to transfer this technology so that it can be used in Latin American countries.

Community Epidemiology Workgroup members have also begun to monitor the epidemiology of AIDS in their areas since more than 25 percent of AIDS cases are IV drug users. For example, almost a third of the 3,700 AIDS cases in New York City involve intravenous drug use. Since 18 percent of these cases were females, intravenous drug use is considered the most prevalent risk factor for women. It was also reported that the concern regarding AIDS has caused some drug users to alter their needle sharing behavior. In Harlem, for example, several vendors have begun packaging a combined bag of heroin with a hypodermic needle — called "Check Mate."

In addition to our epidemiologic research accomplishments, NIDA provides expert consultation to other Federal agencies on technical matters of survey design, sampling techniques, and questionnaire construction. For example, the drug consumption estimates for the Department of Justice report entitled, "Narcotic Intelligence Estimates" were improved as a result of input from NIDA researchers. Through the publication by NIDA's Division of Epidemiology of a Monograph entitled, "Cocaine Use in America: Epidemiologic and Clinical Perspectives" a major contribution to our understanding of the epidemiology of cocaine also provided input into defining the target population for the cocaine prevention campaign. A NIDA researcher also served as a civilian representative on the planning committee for the Department of Defense 1985 world wide survey of alcohol and drug use.

EXTRAMURAL RESEARCH PROGRAMS

Recent Research Findings

Data from the Drug Abuse Warning Network, the High School Survey and the National Survey on Drug Abuse are used by NIDA researchers to investigate a number of drug abuse issues. For example, in one study entitled "Drug Use by Teenagers and Older Family Members" it was demonstrated that drug use by teenagers was positively correlated with drug use by fathers, mothers and older siblings. The most consistent relationship in this study was between marihuana use by youth and use of the drug by the adults. Another study indicated that increases in cocaine use in the 26 and older population were only partially explained by the aging of the population that had been in their mid-twenty's in 1979. This study demonstrated that a significant portion of individuals aged 26 and older had actually initiated cocaine use at age 26 or beyond, thereby suggesting that the period of risk of initial cocaine use may be longer than for other drugs. Further analysis of the new cocaine users age 26 and older suggested that such users were more likely than the general population of the same ages to be unmarried, employed, college graduates, residing in a metropolitan area and in the western United States. Field studies on the availability of coca paste in Miami and New

York suggested that there was no evidence of widespread coca paste smoking in New York City or South Florida during the first half of 1985.

Another study entitled, "Influence of Privacy and Self Reported Drug Use by Youth" concluded that reporting of drug use by youth is affected by the degree of privacy during the interview, even when a self administered answer sheet is used by the respondent. This finding underscores the importance of achieving maximum privacy when conducting drug surveys and raises questions regarding the validity of data from surveys in which adequate privacy is not obtained.

In a NIDA published study entitled, "Epidemiology of Heroin 1964 to 1984" a combination of field studies, ethnographic studies and sophisticated analyses of existing data bases indicated that during the two decades between 1964 and 1984 there were at least four heroin epidemics which were generally defined in terms of the supply, source and/or region of the country affected. In 1986, NIDA plans to conduct a study to estimate the prevalence of heroin addiction in the United States. An estimate of this type has not been made since 1981 and is long overdue. The purpose of the study is to develop robust, statistically defensible methods for, and estimates of, the number of heroin addicts in the United States for each year 1977 through 1986, by race, age, sex and region. It is anticipated that the methods developed for this particular study will advance the state-of-the-art of estimating drug abuser population sizes.

Significant accomplishments were also achieved by NIDA grantees. These include the conduct and publication of highlights from the High School Senior Survey and analysis of the follow-up data from the survey on the issue of cocaine. This analysis of the longitudinal data from the High School Survey showed quite clearly that cocaine use increases significantly after high school.

Both national surveys, and indepth studies conducted by Drs. Bentler and Newcomb; Kandel; and Cisin, Miller, and Harrell, have indicated that cocaine is emerging as a new drug among young adults who were previously considered beyond the age at risk for initiating drug use. Through their studies at UCLA, Drs. Bentler and Newcomb found significant recent increases in cocaine use in their California cohort. In her New York study, Kandel found that the greatest risk of first cocaine use occurred in the 20 years and older age group, while the age of risk for other illicit drugs occurred earlier. Moreover, Cisin, Miller and Harrell estimated rates of cocaine use based on a national survey of males 18 years and older conducted by Gallup. They found the levels of cocaine use in 1984 to be as high as those based on the 1982 National Household Survey. We cannot tell at this time whether cocaine use has stabilized or whether it has reached a plateau before increasing further.

Even though all grantees work to improve their methodology, several NIDA grantees have specifically developed methods to be used by others to improve data gathering and analysis in the drug research field. In Washington, D.C., Dr. Ira Cisin and his associates are currently working on a technique to improve gathering self report data on illicit drug use. New statistical techniques to deal with the unusual mathematical characteristics of drug use data are currently under development by Drs. Bentler and Woodward. Workshops and exchange programs for national and international drug researchers have been conducted by Bentler and his colleagues to share their new statistical techniques.

Future Plans for Epidemiologic Studies

One study conducted by Dr. Robert Pandina at the University of Colorado will be correlating drug use history with the results of medical examinations conducted on a cohort of adolescents studied since 1979. New analytic procedures developed by Bentler and Woodward will be applied to several large Federally maintained data sets. A statistically sound mathematical model will be developed and applied to examine the relationship between heroin availability and the legal, social and medical consequences of its use. Other epidemiologic activities will focus on heroin price and purity data which will be used to examine changes over time in such consequences as crime statistics, emergency room episodes, deaths, and treatment admissions.

II. UNDERSTANDING THE RISKS AND ADVERSE HEALTH CONSEQUENCES OF DRUG USE

Research to determine the adverse health and behavioral consequences of drug abuse has always been a major part of NIDA's research portfolio. It has served several functions. First, it is an essential component of our mission as a public health agency to clarify the risks posed by the addictive disorders. Findings concerning the degree of risk posed by various addictive disorders have major public policy implications. In addition, research in this area has greatly increased the success of our prevention efforts through the dissemination of scientifically accurate assessments of the risks posed by various forms of drug abuse. Finally, it has provided us with information that is vital to the development of more effective prevention and treatment strategies.

Current research in this area involves: studies of the effects of drugs on the function of vital organs; studies of the effects of drugs on reproductive function and, in particular, studies of the effects of maternal drug use on fetal development. Other studies investigate the effects of drug use on cognitive development; the effects of drugs on immune system function; and, the effects of drugs on the performance of complex cognitive and psychomotor tasks.

EXTRAMURAL RESEARCH PROGRAMS

Epidemiologic Studies of Adverse Health Consequences

Early in 1985, NIDA and the Centers for Disease Control collaborated in an epidemiologic field study designed to find victims of MPTP. The substance MPTP, a contaminant of the synthetic narcotic MPPP, causes Parkinsonism when injected intravenously. During investigation [illegible], approximately 350 known or suspected MPTP victims have been identified, although the number of persons in [illegible] potentially exposed may be much higher. The profound neurotoxic consequences caused by this substance make identification of users, and the [illegible] follow-up of [illegible], especially important since the Parkinsonian syndrome associated with MPTP has so far been largely resistant to [illegible].

HTLV-III Infection Among Intravenous Drug Users

NIDA's current efforts are directed toward [illegible] the spread of HTLV III and AIDS in and among the drug using population and toward addressing the needs of drug users already infected by HTLV III, or diagnosed with AIDS or AIDS Related Complex (ARC). [illegible] have focused on three principal populations: (1) drug users currently infected with HTLV III; (2) other drug users at high risk of [illegible] the disease; and (3) drug abuse treatment and [illegible] personnel. [illegible] should continue to be major foci of the Institute's efforts in this area, NIDA is formulating a broader look at the problem of HTLV-III infection and AIDS. Specifically, the Institute is incorporating the growing knowledge and concern about HTLV-III disease into its overall prevention and treatment strategy. By increasing public awareness of AIDS as a significant health consequence of drug use, we may well be able both to increase the effectiveness of our current drug abuse prevention and education efforts and encourage large numbers of current drug users, especially IV drug users, to enter treatment. Success in these two areas are capable of rewarding us with not one, but two, major long term dividends-- reduced numbers of drug users and reduced numbers of AIDS/ARC patients.

Specific NIDA activities to clarify the role of drug use in the spread of HTLV-III and the subsequent development of AIDS include efforts to:

- Clarify the epidemiology and natural history of HTLV-III infection in IV drug users. NIDA will continue to conduct investigations into the epidemiology of HTLV-III infection, AIDS, and ARC.

- Stimulate and support research and development of effective intervention approaches and treatment agents related to HTLV-III disease among the drug using population. In addition to epidemiologic studies (e.g., etiology, risk factors, and natural history), NIDA continues research on effective prevention strategies, drug detection and treatment interventions, and preclinical studies regarding the effects of drugs of abuse on the immune system.

Effects of Marihuana Smoking

Marihuana and the Immune System

There have been a number of studies over the past decade, both in man and in experimental animals, indicating the possible deleterious effects of marihuana on the immune (defense) system. With the continued widespread use of marihuana and especially [illegible] in therapy for cancer patients, it is important [illegible] effects of THC, marihuana and other cannabinoid preparations such as [illegible] (THC) [illegible] on immunity, either in a [illegible]. In recent studies [illegible] of microbial infections [illegible] with both viral and bacterial [illegible], the sensitivity to infection [illegible] with various herpes [illegible] THC has an increased incidence of [illegible] [illegible] effectively [illegible]. The mechanism for this [illegible] the suppression of a variety of components of the immune system has been suggested. The possible role of marihuana suppression of the immune system in the pathogenesis of Acquired Immunodeficiency Syndrome (AIDS) is currently under investigation.

Pulmonary Effects in Male Subjects

Since the smoke of marihuana contains many of the same respiratory irritants found in tobacco smoke, in addition to approximately 60 cannabinoid compounds, there is concern over the potential long-term pulmonary consequences of regular marihuana smoking. That harmful effects of marihuana on the lungs can, in fact, occur, is suggested by the results of several studies conducted over the past decade on whole animals, lung tissue and isolated cell systems exposed to marihuana smoke, as well as by observations in clinical studies.

An extensive clinical research project at UCLA was initiated to test two major hypotheses. One hypothesis was that habitual smoking of marihuana may be a risk factor for the development of functional respiratory impairment, or respiratory disease, and that cigarette smoking may have additive or synergistic effects to those of marihuana on lung function and/or respiratory symptoms. The other hypothesis was that habitual marihuana smoking may produce histologic abnormalities in bronchial mucosa indicative of inflammatory, hyperplastic and/or metaplastic changes, analogous to the abnormalities noted by others, in tracheal biopsies from 23 habitual smokers of hashish and tobacco. In addition, they wished to evaluate whether regular tobacco smoking may add to or potentiate the morphological effects of marihuana on the tracheo-bronchial epithelium. To test these hypotheses, during the first three years, the investigators recruited a total of 284 heavy, habitual marihuana smokers and 171 control subjects. The subjects are divided into four groups: marihuana-only smokers, tobacco-only, smokers who currently use both substances and a group of controls who don't smoke at all. Reliability of the questionnaire responses concerning tobacco and marihuana use was assessed by measurement of plasma cotinine, cannabinoids and blood carboxyhemoglobin. A number of sophisticated lung-function tests had been carried out on a majority of the recruited subjects and bronchoscopy with histological examination had been performed in a substantial subsample of the population. Preliminary data indicate significant pathology in the user groups, some of the tests indicating more pathology in the tobacco only group than in the marihuana only group or controls, while other tests (such as airway resistance) indicated more abnormality in the marihuana group than in the tobacco smoker or control groups. The multiple user (marihuana and tobacco) group had the most extensive epithelial alterations suggestive of additive damaging effects of the two substances used.

Prenatal Exposure to Drugs

It has become obvious from both animal experiments and clinical observations that the placenta does not act as a barrier to protect the fetus from exposure to drugs taken by the mother. Nearly all drugs or foreign chemicals, following maternal exposure, enter the fetus and may exert adverse effects, depending on the reactivity of the drug in the fetus and the extent of fetal drug exposure. The fetus may be affected through the direct action of a drug as well as indirectly due to drug effects on the mother.

Drug disposition plays an important role in the elicitation or termination of pharmacologic effect. The biotransformation of drugs or other exogenous chemicals in the placental-fetal unit was summarized in a recent NIDA publication (Research Monograph #60, *Prenatal Drug Exposure: Kinetics and Dynamics*), published in 1985. Recent findings in this area suggest that fetal liver and placenta of human and nonhuman primates develop drug-metabolizing enzymes during gestational maturation, while other subprimate animals in general lack enzyme activities at this stage. One set of drug-metabolizing enzymes in the placenta has been found to exhibit increased activity in tobacco smokers. Preliminary evidence suggests that these enzymes may lead to the production of certain metabolic intermediates capable of eliciting deleterious effects in the fetus and the newborn. Since research in this area is still in a developmental stage, continuing efforts are required to establish the toxicological or pharmacologic significance of these drug-metabolizing enzymes.

Other NIDA sponsored research has studied the prenatal effects of tobacco and its constitutents, diazepam, and opiates. Studies by Dr. Richard Miller at the University of Rochester confirm findings that cigarette smoking is associated with small birth weight for infants, postnatal growth retardation, and other delays in development. In particular, cadmium a toxic by-product of tobacco smoke, has been documented to be present at higher levels in placentae of cigarette smokers than in non-smokers. In both animal studies and in vitro human placenta perfusion studies, cadmium has been found to be placental toxic. Other studies by Dr. Miller indicate that persistent and selective alternation of the central nervous system is induced in rats following low-dose diazepam exposure during the last week of gestation and that coadministration of a diazepam antagonist effectively prevents these alterations. The adverse effects of opioids on the offspring due to maternal drug exposure have been well documented, although the mechanisms of action are not yet entirely clear. *In utero* monitoring, utilizing the pregnant ewe model, of the direct effects of morphine exposure on fetal behavioral, respiratory, and cardiovascular functions are examined by Dr. Hazel Szeto at Cornell University Medical College in New York. Results from her studies show that morphine exhibits a dual dose-response relationship--excitation at low dose, and suppression at high dose, and a fetal narcotic abstinence symptom can be precipitated *in utero* after a short two-hour low dose morphine exposure. These findings suggest that the fetus may undergo a cycle of acute physical dependence and withdrawal when opiates are administered to normal clinical patients. Further research in this area is needed to provide insight into the mechanisms of neurobehavioral disturbances observed in children born to pregnant narcotic users.

Health Effects of Marihuana Smoking in Female Subjects

In view of increasing prevalence of smoking in women of child bearing age, and the existence of abundant evidence from animal studies that cannabis is capable of inducing hormonal imbalance leading to possible reproductive malfunction, it was deemed important to study the possible hazards of marihuana smoking in female volunteers. In a currently funded study, carried out at McLean Hospital in Boston, clinical observations suggest that marihuana smoking may indeed induce significant abnormalities in both reproduction function and pulmonary function in otherwise healthy adult females.

Smoking a single 1 gram marihuana cigarette containing 1.8 percent THC induced a 30 percent suppression of plasma luteinizing hormone (LH) levels in women during the luteal phase of the menstrual cycle. After marihuana placebo cigarette smoking, no LH suppression was observed in the same women studied under double-blind conditions. The biologic significance of a statistically significant acute marihuana induced suppression of LH during the luteal phase of the menstrual cycle remains to be explored. These data are consistent with findings obtained in studies with experimental animals that THC actively suppresses LH levels. These observations also suggest that a shortened luteal phase duration previously observed in women may be associated with marihuana induced suppression of LH during the luteal phase of the menstrual cycle.

To investigate the effects of chronic marihuana smoking on lung function, pulmonary function tests including single breath carbon monoxide diffusion capacities (DLCO) were performed on 26 healthy women who smoked from 1-2 marihuana cigarettes per day for 1-13 years. Control groups included 22 non-smoking and 26 tobacco smoking women. Results revealed that marihuana smoking, with or without tobacco, is associated with a marked reduction in the DLCO which was significantly different from the non-smoking controls. The subset of subjects who smoked marihuana and tobacco had a further reduction of the DLCO. These results suggest that heavy marihuana smoking, when added to tobacco smoking, may damage the gas exchange surface of the lung.

Psychomotor Stimulants and the Cardiovascular System

Cocaine and other psychomotor stimulants have significant effects on the cardiovascular system. This action is largely due to the cocaine-induced blocking of neuronal uptake of norepinephrine and increased sympathetic tone and/or reactivity. However, as yet only the effects on heart and blood pressure are well documented. In spite of large use of these drugs in our society there is a paucity of data with regard to their effects on the cardiovascular, hemodynamic and vascular status in the CNS. Cocaine's chronic use, unlike that of opiate drugs, does not appear to be associated with the development of tolerance to all of its CNS actions. Thus a number of important questions need to be addressed which will help us understand the toxicological and pharmacological profile of cocaine and other psychomotor stimulants. For example:

- o Are the cardiovascular effects of chronic or acute cocaine use complicated during stress or exercise? The question is relevant because cocaine may stimulate an increase in the number of cardiac beta adrenergic receptors and may thus potentiate the cardiac effects of increased catecholamine levels. Such potentiation could precipitate an heart attack.

- o Effects of cocaine on the contractability of cerebral blood vessels and the cerebral microvascular system also need to be examined systematically. Some investigators in the field believe that psychomotor stimulants, e.g., cocaine and amphetamine, may be involved in the causation of cerebral arterial spasm which is a major cause of morbidity and mortality. This issue needs to be clarified.

Health Hazards of Abused Inhalants

The intentional inhalation of solvents for their psychoactive effects, especially by children and teenagers, has become prevalent worldwide and has caused considerable concern and alarm. As with any biologically active agent, the acute effects of solvent inhalation are generally a function of dose and can range from little or no effect to death. Related to the acute pharmacologic effects are the dangers from the solvent, although not lethal, may cause persisting tissue or organ damage. With repeated exposure, even at relatively low doses, cumulative effects may occur that adversely alter the morphology and/or function of tissues or organs. Such alterations also could result in tolerance, thus requiring higher doses to achieve the desired effect and exposing the individual to higher concentrations with the increased risk of damage or death, or in physical and/or psychologic dependence.

A major concern of researchers is that solvents might cause neurologic damage because of their lipophilicity and their obvious pharmacologic effects on the brain. Another concern is that solvent abuse typically starts at a very young age (as early as 7 or 8 years old), and there is the possibility that still-developing tissues and organs may be especially sensitive to toxic insult. Major psychosocial development is also occurring at this age, and any agent that interferes with this development could cause long-lasting psychological problems, including the propensity for further substance abuse.

Toluene

Recent animal experiments have demonstrated irreversible neurophysiological damage in rats after prolonged exposure to toluene vapors, [illegible] just after weaning to toluene showed a progressive decrease in motor activity during the first six weeks of exposure, after which apparent tolerance developed. There was no behavioral or electrophysiologic evidence for any peripheral neuropathy as was seen with exposure to n-hexane, which was examined concurrently. However, a component of the brainstem auditory-evoked response was depressed. Further examination revealed that the rats were partially deaf as measured both behaviorally and electrophysiologically. A series of experiments were then conducted to characterize this apparently specific sensory effect of exposure to toluene. The major findings were: (1) weanling rats were more sensitive to the effect than young adults; (2) the hearing loss was frequency dependent, being greater at higher than at lower frequencies; (3) there was damage to and loss of receptor (hair) cells in the cochlea; (4) the effect was concentration, duration, and exposure schedule dependent with clear hearing loss seen after only three days of exposure, and (5) subcutaneous injection of toluene resulted in similar toxic effects.

The finding that toluene and related solvents are clearly a factor in causing deafness in rats raises the possibility that other adverse effects have gone undetected in animal studies because of inadequate exposure schedules, use of inappropriate species, and/or measurement of the wrong parameters. The human syndromes associated with abuse of toluene-containing solvents include cerebellar ataxia, motor disturbances, cerebral and cerebellar encephalopathy, optic neuropathy and other visual problems, and some evidence for auditory dysfunctions. Only the last symptom has been clearly established in the laboratory as an effect of exposure to toluene. If toluene is responsible for any of the other symptoms described, then it should be possible to reproduce some or all of these symptoms in an appropriate animal model. Until that is done the role of toluene in causing any other symptoms will remain unresolved.

Benzene

The hematopoietic and potential carcinogenic effects of benzene are well known. As a result fairly strict standards for its use are in effect in the United States. Nevertheless, the presence of benzene as a contaminant in various mixtures containing toluene [illegible] a potential toxic hazard in solvent abuse. Aside from benzene's well established myelotoxicity, damage to other organs and tissues has not been demonstrated to be great. However, such potential toxicity has not been investigated in the context of solvent abuse, where substantial concentrations may have been inhaled even though the concentrations in the mixtures are low.

The acute pharmacologic effects of benzene are, like toluene, concentration dependent, with higher concentrations causing central nervous system depression, cardiac arrhythmias, and death [illegible]. These higher concentrations would not be expected to be attained from inhaling the fumes from currently available products. Clinically, the major concern is with possible damage resulting from chronic inhalation of lower concentrations, and not much information is available on these effects.

Solvent Mixtures

Only a few animal experiments have examined the pharmacologic and neurotoxicologic effects of exposure to solvent mixtures. The main experimental results have come from Mexico where the effects of commercial paint thinners thought to be abused locally have been studied in rats, rabbits, and cats.

The "thinners" used by these different groups of investigators all contained substantial amounts of toluene, ranging up to 40 to 80 percent. The other components that were present in lesser amounts-- including methanol, hexane, benzene, xylene, and acetone-- differed markedly in their proportions among the different thinners. Thus, identification of the component(s) responsible can only be speculated on without further systematic investigation.

Other NIDA supported investigations, conducted by Dr. Pryor and his associates, described the acute concentration-related pharmacologic effects when rats were exposed to a solvent mixture made up of paint remover (methylene chloride and methanol) and paint thinner (toluene, heptanes, and xylenes). The syndrome consisted of ataxia, falling, hind-limb flaccid paralysis, abnormal scratching, head jerking, and finally prostration, unconsciousness and death with increasing concentrations. Experiments with the separate components of the mixture revealed that the hind-limb flaccid paralysis and head jerking were associated exclusively with exposure to methylene chloride, whereas the abnormal scratching was caused by the toluene. These results emphasize the markedly different pharmacologic (and, by extrapolation, neurotoxicologic) characteristics of various solvents, even though they may all be, and have been, generally described as CNS depressants. The findings also clearly demonstrate that the effects of exposure to a solvent mixture cannot be simply predicted from the known pharmacology of the components or vice versa.

The most complex mixture of all, gasoline, has received only scant attention in animal experiments for its pharmacologic and neurotoxic effects, despite its abuse and reported CNS damage. In later studies conducted by Dr. Pryor, weanling rats were exposed to the fumes from leaded or unleaded regular gasolines. A battery of neurobehavioral tests administered at intervals throughout the exposure phase and for 8 weeks thereafter did not reveal any persisting effects suggestive of permanent damage. However, the rats exposed to the leaded gasoline, but not the unleaded gasoline, took longer to learn a radial maze than controls or [illegible]. This cognitive deficit was tentatively attributed to the tetraethyl lead in this gasoline, although other compounds could not be ruled out.

Other NIDA supported epidemiologic studies are now collecting data to examine the effects of drug use on health and functioning. At the University of Colorado, Dr. John [illegible] will evaluate the relationship of drug use to health behaviors in a sample of adolescents. Another study by Dr. Benjamin Zablocki will examine the effect of long term marihuana use on pulmonary functioning. Finally, with NIDA support, Dr. Karen Kerner is preparing a source guide on inhalant use which will report on what is currently known about the consequences of inhalant use.

INTRAMURAL RESEARCH PROGRAMS

Actions of Amphetamine and its Analogs

Amphetamine and chemically related analogs are commonly abused by users because of their stimulant euphorigenic properties. The abuse of amphetamines can lead to a series of adverse effects on the nervous system, the seriousness of which depends upon the duration and quantity of amphetamines abused. Adverse effects include headache, dizziness, agitation, confusion and disturbances of thought processes. Severe intoxication can lead to extreme mental disorders, which some investigators feel closely resemble schizophrenic and manic depressive psychoses. Paranoia with auditory and visual hallucinations also results from chronic abuse of high doses of amphetamines. Understanding the mechanism of these drug's toxic effects is important not only because they can produce such dramatic adverse effects, or because of their widespread use in the treatment of attention deficit disorders and obesity, but because illicit manufacture of several amphetamine analogs has recently caused serious health problems.

MDMA and MDA: Mechanisms of Action

MDMA has recently been temporarily placed in Schedule I of the Controlled Substances Act under emergency scheduling procedures. This decision was based on data indicating that MDMA, like MDA, which has no known legitimate medical use, exhibits pharmacological properties which contribute to its high potential for abuse. The psychoactive properties of these substances are supported by scientific data and by evidence indicating that MDA and MDMA are increasingly found in illicit drug traffic.

MDMA (3,4-methylenedioxymethamphetamine) is an N-methyl analog of the Schedule I substance MDA. Both compounds are structurally related to amphetamine but exhibit psychotomimetic as well as stimulant properties. Behavioral data suggest that MDA elicits substitutive responses similar to those elicited by amphetamine, hallucinogens and cocaine. In addition, recent studies indicate that MDA is a potent neurotoxin which destroys serotonin neurons in the rat brain. To date, the precise mechanism of action of these substances is not known. It is important therefore that the neurochemical mechanisms of action of MDA and MDMA be elucidated in order to understand their abuse potential and neurotoxic effects on various brain systems.

Substances of abuse exert their effects through brain recognition sites associated with specific neuronal pathways. Biochemical and neuroanatomical techniques will be used to determine the specific neuronal systems associated with the pharmacological effects of MDA and MDMA.

Neurochemical techniques will then be applied to elucidate the specific mechanism by which MDA and MDMA alter brain chemistry. Our initial studies indicate that although behaviorally similar to amphetamine, cocaine and the hallucinogens, both MDMA and MDA exert potent effects on brain recognition sites distinct from those associated with the actions of common stimulants and hallucinogens. This information will be applied to studies involving the acute and chronic administration to rats of MDA and MDMA. Such studies will provide information about the short and long term biochemical changes and/or neurotoxic effects associated with the use of these substances.

III. DEVELOPING AND PROMOTING EFFECTIVE DRUG ABUSE PREVENTION ACTIVITIES

The ultimate goal of most, if not all, our research programs is to develop effective prevention programs that will inoculate individuals from the risk of drug use. The need for effective prevention efforts has never been more evident, for, in spite of the tremendous progress that has been made in efforts to control the availability of illicit substances, opportunities to use illicit drugs remain common. Nevertheless, by reducing the demand for drugs in this country it is likely that major reductions in the supply of illicit substances will follow.

NIDA's prevention program has concentrated in three major areas: abuse liability studies which are intended to restrict, through scheduling of drugs under the Controlled Substances Act (CSA), the availability of new substances with high abuse potential; research to understand the factors involved in the initiation, progression, and maintenance of drug abuse behavior; and, studies to evaluate and replicate new prevention programs.

Abuse liability

An important, but often underrecognized, component of NIDA's research program involves efforts to restrict the availability of new substances with a high potential for abuse. This research grew out of the Drug Abuse Prevention and Control Act of 1970 (also known as the Controlled Substances Act) which obligates the Secretary of the Department of Health and Human Services (DHHS) to provide advice on the abuse potential of new substances to the Department of Justice for consideration in scheduling drug control actions. NIDA shares, with the Food and Drug Administration, the lead role in HHS for developing information on drug abuse and making recommendations pursuant to the Psychotropic Convention. One important component of this program is the development of methods to use for evaluating the potential abuse of particular substances. While this work is often conducted in animal models, it has resulted in vital theoretical as well as practical findings.

Risk Factors

As with any disorder, risks posed by the addictive disorders appear to vary from individual to individual. Even where drugs are readily available and abuse is common, not all individuals try them. Among those that do, only a relatively small number progress to regular use, and, of these, only a portion become compulsive users. Identifying and understanding factors which predispose individuals to addictive disorders are critically important for prevention and treatment efforts. Because of potential benefits of findings in this area, NIDA has initiated research ranging from basic studies of genetic variability in brain systems to clinical and epidemiological studies to identify and clarify factors which affect vulnerability to addictive disorders.

Current research in this area involves: investigations of possible genetic or other biological factors which may increase vulnerability to addictive disorders; investigations of environmental factors which may increase or decrease the vulnerability to addictive disorders; and, studies of psychological factors which may increase or decrease one's vulnerability to addictive disorders. In addition, during the past year, efforts have expanded to include epidemiologic studies of the relationship between drug abuse and HTLV-III diseases.

Program Evaluation

One of NIDA's highest priorities is to evaluate the effectiveness of prevention programs. Our current efforts in this area are focused largely on evaluations of the effectiveness of school-based, family, and community prevention approaches.

EXTRAMURAL RESEARCH PROGRAMS

Abuse Liability Program

NIDA is the lead Federal agency responsible for the assessment of abuse potential of substances which act on the central nervous system. The general purpose of this program is to obtain information about abuse potential of various drugs by means of a battery of tests in laboratory rodents, monkeys and baboons as well as to obtain data pertaining to relative abuse potential of drugs within drug classes. This research has been an important part of NIDA's mission since its inception in 1974. In the upcoming years, this research will assume an even greater importance because of the increasing problem with illicitly synthesized drugs ("Designer Drugs"), and increased consciousness of the public about the problems of drug abuse. The Drug Enforcement Administration is identifying increasing numbers of new synthetic drugs on the street. Moreover, various Government agencies are increasing their efforts to control the trafficking of the drugs of abuse. The data regarding the abuse potential of these synthetic drugs are very scarce. NIDA has a statutory obligation in the Department of Health and Human Services to generate these data. The data generated are used by the Assistant Secretary for Health and the Drug Enforcement Administration to make recommendations and decisions, respectively, pertaining to scheduling of drugs under the Controlled Substances Act of 1970. Moreover, NIDA and the Secretary, HHS, use the data generated from this program to make international scheduling recommendations pursuant to the United States participation in the Psychotropic Convention.

There are two major centers of contract supported research, and one major and seven relatively smaller individual grant supported projects in the abuse liability area. The following is a brief description of these research projects.

Johns Hopkins University

Dr. Joseph Brady is the Principal Investigator of this project which focuses on studying the reinforcing properties of a variety of drugs in baboons, especially psychomotor stimulants and sedatives. The baboons are fitted with surgically implanted catheters in the jugular vein. These catheters are connected to drug solutions or saline. The animals are trained to self-administer cocaine. When stable self-administration behavior to cocaine has been established, test drugs are substituted. If the animal self-administers the test drug, the drug is considered a reinforcing agent. Generally excellent correlation has been established between reinforcing properties and abuse in man. Over the years, Dr. Brady has compiled a dictionary of drugs affecting the central nervous system in terms of their reinforcing properties in baboons.

Dr. Brady and coworkers have also assessed the relative abuse liability of eight widely prescribed appetite suppressants. They have determined how hard baboons will work for these drugs. For example, a baboon is trained to press a lever 240 times in order to receive a drug injection. The required number of lever presses is then doubled several times. The baboons then reach a "breaking point", a point beyond which they will not work for their drug. This gives a measure of relative reinforcing potency of drugs within a class.

The Hopkins group has been at the forefront of method development for the assessment of abuse liability of drugs. Methods to assess reinforcing properties of drugs by the oral route and intragastric route have been developed. These methods permit assessment of abuse liability of drugs with very low water solubility. Currently, Dr. Brady and his team have been working on the assessment of the relative abuse potential of benzodiazepines. They have shown that diazepam can produce signs of physical dependence in baboons after as little as 7 days of drug administration using a benzodiazepine antagonist, Ro 15-1788. Recently, they have initiated the testing of MDMA.

Medical College of Virginia

Dr. Louis Harris at the Medical College of Virginia has been concerned primarily with assessment of abuse liability of narcotic agonists, antagonists, and mixed agonists-antagonists. Using a blind method, unknown compounds are studied in a series of rodent tests for their analgesic properties. Compounds deemed promising are studied in morphine-dependent rhesus monkeys maintained with morphine. The monkeys are withdrawn from morphine for 14 hours after which the test drug is given. At this time the monkeys show a characteristic withdrawal syndrome. Test drugs that relieve or attenuate this syndrome are considered morphine-like. Morphine dependent monkeys can be given a test drug without being withdrawn from morphine. If the test drug precipitates withdrawal, it is considered an antagonist.

Additional tests include a physical dependence test. Monkeys receive the test drug in maximally tolerated daily doses for 28 days. Some are abruptly withdrawn. If signs of withdrawal are seen, the test drug is considered to produce physical dependence. Some monkeys are challenged with an injection of naloxone, the standard narcotic antagonist. If signs of withdrawal occur after naloxone challenge, the test drug is considered to produce physical dependence. Other tests that are run with drugs of great scientific interest include a rat intraperitoneal infusion test and self-administration procedures in rhesus monkeys.

University of Michigan

Dr. James Woods heads the Drug Evaluation Unit of this multidisciplinary grant which deals with the assessment of abuse potential of narcotic agonists, antagonists, and mixed agonist-antagonists. There are four projects which make up the drug evaluation unit. The primary objective of this projects is to continue to evaluate the effects of compounds on receptor binding, mouse vas deferens, morphine dependent and withdrawn monkeys, monkeys trained to self-administer codeine, and monkeys trained to discriminate the interoceptive effects of either cocaine or ethylketocyclazocine. After receiving the preliminary rodent screen data, the investigators test compounds blind in a series of in vitro tests including guinea pig ileum, and mouse vas deferens and tissue binding studies. Compounds deemed of interest are then tested in the monkey paradigms described above. In general, if the compound to be tested, is available in small amounts, it is assigned to Michigan since in vitro tests give a lot of information for a small amount of drug. Medical College of Virginia conducts tests if candidate agents are available in large amounts. Quite frequently the test compounds are sent to both facilities, and their results are compared. Standard drugs are sent to both programs as quality control devices. Data generated by these laboratories are in agreement almost 100 percent of the time.

Other Abuse Liability Projects

In addition to the above three major extramural centers of research in abuse liability area, NIDA is funding seven grants which focus on some aspect of abuse potential of drugs in animal models. However, the emphasis in these projects is more on behavioral or basic research and on understanding of underlying mechanisms of physical dependence, self-administration and reinforcement. Drugs which are currently under study include benzodiazepines, PCP, barbiturates and inhalants.

Risk Factors-- Psychiatric and Etiologic Influences

As with any disease, the risk posed by the addictive disorders appears to vary from individual to individual. Even where drugs are readily available and drug use is common, not all individuals try them. Among those that do, only a relatively small number proceed to regular use, and, of these, only a portion become compulsively involved in use of the drug. If we could understand the factors which appear to make some individuals more vulnerable to the addictive disorders than others, we could greatly improve our prevention and treatment efforts. Because of the potential benefits of findings in this area, NIDA has initiated research along a broad range of fronts, from basic studies of genetic variability to broad epidemiological surveys, to identify and clarify those factors which effect vulnerability to the addictive disorders.

Current research in this area involves: investigations of possible genetic or other biological factors which may increase vulnerability to addictive disorders, investigations of environmental factors which may increase or decrease the vulnerability to addictive disorders and clinical developmental studies to determine the psychiatric and biologic factors which predispose individuals to initiate, escalate and maintain drug abuse. Research on these psychiatric and biologic factors is expected to be expanded in the future as they are crucial to the further development of more effective prevention programs.

Epidemiologic Studies

Epidemiological research supported by NIDA has greatly furthered our knowledge of the distribution, natural history and consequences of illicit drug use. Sophisticated, improved methods for collecting and analyzing drug data have been developed under NIDA's auspices. Several studies have found risk factors, such as predisposing personality or behavioral factors as well as parental [illegible] and peer pressure, that appear to affect the initiation and continuation of illicit drug use. Research in the past year continues to [illegible] clarify the relationship of known risk factors to drug use by examining how ethnicity, age at initiation and sociodemographic characteristics may affect the relationship on a prolonged basis. With NIDA support, Dr. [illegible] has found that individuals who had lived at least one year in [illegible] were [illegible] influenced by the [illegible] peer group's [illegible] smoking [illegible] than by [illegible] predisposing personality or family factors. For example, those [illegible] who [illegible] [illegible] were [illegible] likely to use drugs after [illegible] their [illegible].

Other NIDA researchers [illegible] the [illegible] of the impact of the various risk factors on drug use. In [illegible], Drs. [illegible] and [illegible] found that [illegible].

Some of the [illegible] of the level of their drug use. Furthermore, he and his associates found that adolescents who felt inadequate and insecure were more likely to drink and to engage in delinquent behavior.

In a study of adolescent drug use in New York, Dr. Denise Kandel found that drug users were less likely than nonusers to participate in such adult role behaviors as marriage and parenting. Bentler, in contrast, found that drug users either married and had children earlier or did so later than the adult norm. Bentler also pointed out the possible effects on marriage and the family of adolescents participating in such behaviors before they were properly prepared for these responsibilities.

Program Evaluation and Development

In the area of school-based programs, an approach based on social learning and problem behavior theories has been used with success. It focuses on substance use and the skills needed to resist social influences to use drugs. Youth learn to identify messages and pressures from peers, their families, and the media to use tobacco, alcohol, and marijuana. They also learn specific techniques for resisting or "saying no" to those pressures. This approach focuses on a variety of social skills in addition to social resistance skills. Many of these skills are not directly related to substance use, but helping youth deal with other developmental challenges, and to feel more confident in themselves, will make them less inclined to abuse drugs.

NIDA has also conducted studies of the effectiveness of prevention programs focused on the family and the community. In several studies, the effectiveness of brief, systems-oriented family therapy in the treatment of adolescent drug abusers and in the prevention of drug abuse among younger family members is being explored. One group of studies seek to determine if growth and change through brief, systems-oriented family therapy can result not only in decreased adolescent drug use, but also in effective primary prevention of future family problems, including avoidance of drug use among siblings. In another, family life skills training approaches, which seek to develop effective parenting skills and improve interaction patterns, is being tested.

NIDA intends to build on the information and experience gained from the currently developed and implemented prevention programs. Using this foundation, programs will be developed which will first identify and second, intervene with those at high risk for drug abuse as early in the development of the behavior pattern as possible. Strategies and techniques for prevention programs for general population applications will be enhanced to reflect information gained from ongoing more intensive research studies.

NIDA is supporting research efforts to assess the social and behavioral status of various populations at risk for AIDS Related Conditions (ARC) and for AIDS. Information now being generated by these studies is being utilized to develop health promotion and disease prevention programs.

INTRAMURAL RESEARCH PROGRAMS

Abuse Liability Assessment

Through its Preclinical Research Branch and its Biology of Dependence and Abuse Potential Assessment Laboratory, the Addiction Research Center (ARC) determines the abuse liability of selected compounds in animals and human volunteers. Studies conducted at the ARC and other laboratories have shown that drug dependence is an orderly biological process. Systematic strategies have been developed over the past 50 years to quantitate the role of a variety of specific behavioral and pharmacologic factors in the establishment, maintenance, and treatment of drug dependence. These strategies form the backbone of current and proposed research designed to study the biological basis of drug dependence at the Addiction Research Center. Because of scientific, ethical, and practical considerations, other studies are conducted with nonresidential subjects during brief daily visits to the laboratory. Most studies are collaborative and multidisciplinary in nature, and involve the electrophysiology and psychometric sections of the cognitive laboratory, the diagnostic capabilities of the psychopathology and vulnerability laboratories, the neuroendocrine and pharmacokinetic response assessment capabilities of the chemistry laboratory, and the expertise of scientists of the preclinical and neurosciences branches. With such multidisciplinary efforts it is possible to quantify the subjective, physiologic, behavioral, electroencephalographic, cognitive, pharmacodynamic, pharmacokinetic, reinforcing, aversive, and toxic effects of drugs.

Three major current streams of research involve studies of specific drugs or category of drugs such as: cocaine and other stimulants, mixed agonists and antagonists, and nicotine.

Any specific drug may produce a variety of subjective, behavioral, and physiologic effects. Quantification of these effects, and the relationship among the effects is critically furthering our understanding of the underlying biologic mechanisms by which drugs produce dependence. It is also of practical importance in gaining a better understanding of the interrelations among various effects of dependence-producing drugs so that we can accurately and efficiently predict the abuse liability of new compounds. The corollary to this is the development of new therapeutic agents with lower abuse liability. For instance, the observation that the degree to which an analgesic produces a morphine-like subjective response is a valid predictor of abuse liability, has greatly diminished the need for much more costly and somewhat more difficult direct addiction and withdrawal studies. Similarly, understanding the relations between the reinforcing and punishing properties of abused drugs on learned behavior, and the effects of such drugs on subjective responses, are critically important to furthering our understanding of the mechanisms underlying dependence, and will likely affect our basic experimental and applied diagnostic research designs.

One study currently being developed emphasizes cocaine and will involve the assessment of compounds currently used or proposed for use in the treatment of cocaine dependence. Other efforts will involve the assessment of a variety of compounds and combinations of compounds including nicotine, mecamylamine, behaviorally active antihistamines, benzodiazepines, and sedatives. Assessment of the role of anxiety and personality disorder in the susceptibility to abuse of benzodiazepines will be made using laboratory models of anxiety and panic disorder to study the impact of these states on the reinforcing and interoceptive effects of benzodiazepines. Similarly, the role of a history of morphine dependence in determining a person's responsiveness to morphine-like drugs will be assessed by comparing the effects of various opioid agonists and antagonists in a morphine abusing versus nonmorphine abusing subjects.

Finally, a major effort will be in designing studies in such a way as to yield information of importance in determining the vulnerability of various subpopulations to the effects and abuse of various drugs; in part, this will involve incorporation of subject screening data into ongoing and all proposed studies.

IV. DEVELOPMENT OF MORE EFFECTIVE TREATMENT PROGRAMS

While the main thrust of [illegible] prevention programs is our ultimate goal, it is [illegible] that for the foreseeable future, there will remain a need for effective methods for treating drug abusers. NIDA, and its predecessor organizations [illegible] Health Service, [illegible] historically [illegible] in the development of effective [illegible] of treating drug abusers. [illegible] NIDA [illegible] responsible for [illegible] the [illegible].

[illegible]

[illegible]

[illegible]

Development of Therapeutic Drug Delivery Systems

Research data [illegible] therapeutic [illegible] for the treatment of [illegible] investigations [illegible] sustained [illegible] tests have been [illegible] morphine [illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

Drug Abuse Treatment [illegible]

[illegible]

[illegible]

populations; special problems related to particular agents (e.g. cocaine) or forms of drug abuse; as well as the complex interactions between behavioral, pharmacological and treatment variables. Overall, there have been direct efforts to better understand antecedents to treatment, treatment processes (i.e. what goes on in treatment) and the outcome, effects or results of treatment. There is a continuing need to bolster programs and opportunities for training of scientists and in drug abuse treatment research.

Present State of Knowledge

Changing drug abuse patterns in the past several years has been a growing area of concern, extending far beyond the heroin and methamphetamine epidemics of the late 1960s and early 1970s. The variety of drugs available has increased as is further reflected in recent publicity about synthetic analogs of controlled substances. Over the years there was a substantial increase in the number of casual drug users, and the number of dependent individuals also increased dramatically. As the numbers of drug dependent individuals increased, patterns of drug abuse became more diverse and complex. For example, public health issues, such as the identification of intravenous drug users as a major risk group and carrier population for Acquired Immunodeficiency Syndrome, have emerged. It has been estimated that there are nearly a half million heroin addicts in the United States. Cocaine use has become more wide spread and problematic with as many 20 million people trying the drug and 4-5 million current users, of which it is estimated over one million are young adults between the age of 18 to 25. The percentage of admissions to Federally funded treatment during [illegible] for opiates was only [illegible] percent of the total, thereby illustrating the diversity of drugs currently used. That cocaine also is used by more affluent groups, and the likelihood that these users will seek out private rather than Federally supported treatment centers, suggests that the relative proportion and magnitude of the problem is considerably greater than is indicated in Federal treatment data alone. Finally, the prototypic instance of drug dependence represented by tobacco use, a cause of [illegible] excess deaths per year, is engaged in by more than 50 million users, and yet only now are we beginning to understand the complexities of, and treatment techniques for, such socially permitted drug abuse.

The need for additional modalities, i.e. innovative modalities, and refinements in existing treatment strategies has been recognized, and research sponsored by [illegible] and pointed out new directions.

Specific Treatment Approaches

Within modalities, a variety of [illegible] have been [illegible], with emphasis on counseling and [illegible] directed [illegible] drug-seeking behaviors and dealing with [illegible]. [illegible] residential treatment modalities, [illegible] therapeutic communities, have been effective with a subset of drug abusers. However, there is a need to emphasize development of nonresidential treatment techniques for the increasing population of middle class drug users who can ill afford the time, money or social problems inherent in residential treatment forms. Less intensive regimens of counselling may be a feature of outpatient drug abuse treatment programs. Within different program structures, more specialized treatment approaches may be employed, such as individual psychotherapy, behavior modification, family therapy, or use of pharmacological adjuncts, such as antidepressants. NIDA's treatment research has contributed to the development of many of these approaches.

Several treatment perspectives currently of interest and importance to the development of improved drug abuse treatment clinical services are briefly described below.

Behavioral Approaches

NIDA has supported extensive basic and applied behavioral research which has contributed to a better understanding of drug effects, and the complex interactions between pharmacological, behavioral and environmental factors. Scientists developing drug abuse treatment strategies from the behavioral perspective incorporate elements of diverse approaches after implementing a precise analysis of their utility. Behaviorally based techniques have been developed in the context of inpatient and outpatient services and have been applied in the treatment of stimulant, narcotic analgesic, sedatives and other drug use. The programs tend to be individualized and include a thorough analysis of the factors leading to and maintaining drug abuse in an effort to eliminate its occurrence. The general and specific aspects of these approaches have been reviewed in NIDA Research Monographs #46, *Behavioral Intervention Techniques in Drug Abuse Treatment*, #58, *Short Term Cost Effective Treatment Strategies*, and #53, *Pharmacological Adjuncts in Smoking Cessation*.

Examples of behaviorally-based treatment approaches include strategies developed specifically to address:

Cocaine: Behavioral treatment strategies based on contingency contracting methods have been used effectively in the treatment of individuals with severe cocaine abuse disorders. These efforts have been effective with individuals who represent the more affluent drug abusing community, including physicians, dentists, and nurses.

Opioids: [illegible] behaviorally based [illegible] research has been conducted in the past decade involving opioid using populations. The range of effective therapeutic manipulations involving methadone, use of contingent delivery of [illegible] doses (e.g. benzodiazepines such as Valium), [illegible] educational and employment opportunities has been examined. Specific efforts to evaluate the utility of behaviorally-based treatments have been undertaken in both inpatient and outpatient settings. This systematic research has contributed substantially to our understanding of drug abuse and its remediation.

Tobacco: Behaviorally based clinical research on tobacco use has pointed to new directions for the treatment of users of cigarettes and smokeless tobacco. Recent findings of NIDA funded research in this area points to the importance of well integrated behavioral-pharmacological strategies. Impressive one year follow-up results of cessation efforts have been described using these well documented and controlled techniques. In comparing outcomes for three treatment conditions--intensive behavioral treatment, nicotine gum with low therapist contact, and nicotine gum with intensive behavioral treatment--the combined nicotine gum with intensive treatment had significantly higher abstinence rates than either of the other two treatment groups.

Psychotherapy

Recent research indicates that psychotherapy may significantly improve outcomes for seriously depressed methadone maintenance clients, although this finding was not apparent in a second study. Dr. Charles O'Brien recently conducted an analysis of studies on the effectiveness of psychotherapy as a tool in the treatment of opiate addicts and concluded that psychotherapy was generally a useful approach. A study by Dr. Thomas McLellan, and others at the Veterans Administration Hospital in Philadelphia, suggests that the severity of affective disorders may be a significant determinant of the potential to benefit from each treatment, with severely troubled clients more likely to improve than other less disturbed clients. Further investigation of psychotherapeutic approaches is needed to refine and elaborate the potential utility of such treatment approaches for drug abuse clients. Well-designed studies should build on existing psychotherapy treatment assessment research conducted by the National Institute on Mental Health, and address both the conventionally available psychotherapies as well as new brief approaches.

Family therapy approaches have been found to be beneficial in treatment of drug abuse clients. Two approaches used in treatment studies of drug abusing adolescents-- conjoint family therapy and one-person family therapy-- were examined. The results of these studies show that clients in both treatment conditions experienced improvement in reducing drug use, psychopathology, and in strengthening the family structure. The successful use of one-person family therapy, an approach which stresses improvement of family functioning through exploring family problems with the client and suggesting coping strategies, is especially important, since it is difficult to recruit whole families into treatment.

Aftercare and Self-help Groups

In a study of treated opiate users participating in an aftercare program combining both a professionally led recovery training program and self-help approach, it was found that clients receiving organized aftercare services were more likely to be opiate abstinent, or nearly so, than were other opiate addicts who did not receive aftercare attention during a 12 month follow-up period.

Pharmacologic Approaches

Recent research has identified high prevalence rates of other psychopathology among opiate addicts, including major depression, anxiety disorders, alcoholism, and antisocial personality. Some of these conditions — depression and anxiety disorders — are amenable to treatment with pharmacologic agents. In addition, pharmacologic agents may be used to treat the substance abuse disorder itself—for example, methadone for detoxification, and naltrexone during aftercare. Tricyclic antidepressants have been used to improve retention among opiate addicts in treatment programs, and for treatment of depression which is characteristic of cocaine abusers after their use of cocaine has been discontinued.

The Changing Treatment Environment

In the search for more effective service delivery systems, consideration has been given to alternative methods for providing counseling or other therapy services, as well as dispensing pharmacologic agents. Often, outreach services identify drug abusers in need of treatment, but these individuals are resistant to entering conventional treatment programs. Alternative arrangements have been shown effective in engaging these individuals. These include dispensing of methadone to stabilized, employed addicts in the offices of private practitioners or providing home nursing visits to provide detoxification, health services and [illegible] for addicted women.

Treatment Outcomes

There is a considerable body of data about the consequences of treatment, that is, the effectiveness of treatment. Most recently there is an interest in long-term treatment outcome history, although replications of these studies to reflect the changing composition of the drug using population will be necessary in the future. Major conclusions from larger studies such as the Drug Abuse Reporting Program (DARP), the Treatment Outcome Prospective Study (TOPS), are briefly described below.

Existing treatment modalities (methadone maintenance, drug-free outpatient, therapeutic community) are effective in achieving significant, lasting reductions in drug use and related criminal behavior in the community, as well as increases in socially productive behavior (employment, school attendance, etc.). Detoxification alone, however, is significantly less effective in terms of immediate outcomes (i.e. during the first year post-treatment). It must be recalled that these treatments are primarily focused on the traditional models which may not be ideal for serving many of the individuals currently involved in illicit drug use. Increasing diversity in the drug using populations will require increasing diversity in methodology of these longer term studies.

Time in treatment appears to be a significant variable in producing favorable post-treatment outcomes. Those remaining in treatment less than 90 days experience little lasting benefit, while those in treatment more than 90 days are more likely to show dramatic reductions in drug use and criminality, and improvement in overall employment status. In the DARP study, for example, clients in detoxification did no better than a minimum treatment comparison group, while those in other modalities showed increasingly better outcomes in direct relationship to time in treatment.

In a study of therapeutic community clients, the time-in-treatment relationship was also evident. The findings on behavioral outcomes were also accompanied by striking reduction in certain kinds of psychopathological symptomatology among clients in treatment for at least four months. The improvement was evident in a number of areas as reflected by psychological test scores, but particular improvement was found in the dramatic reduction in the number of clients with serious depression. Moreover, the improvement noted was stable over time and well correlated with improvement on behavioral outcomes.

Among some populations of drug abuse clients, multiple treatments are the rule rather than the exception. Among one large sample of clients, for example, 40 percent experienced some previous drug abuse treatment. In following this sample after treatment, it was found that half the clients relapsed and re-entered treatment. This is consistent with the frequent observation that drug abuse must be characterized as a "chronic relapsing disease," and that clients may need repeated treatments in order to achieve lasting improvement.

Even with the high rates of relapse, the percentage achieving lasting drug abstinence tends to increase over time. Dr. D. Dwayne Simpson and his associates at Texas Christian University found that, over a six year period, a sample of opiate addicts could be meaningfully classified into outcome groups on the basis of how and when they achieved or failed to achieve abstinence. While some clients achieved opioid abstinence and avoided such other pitfalls as substitution of alcohol or heavy nonopiate use after a single treatment and maintained this improvement over the entire six year period, others achieved this abstinent status only after relapsing and re-entering treatment one or more times. However, by the end of the sixth year, nearly one-half of the addicts studied had achieved and maintained opioid abstinence for at least one year, up to and including the sixth year. Another 13 percent achieved abstinence after incarceration or [illegible] treatment; thus the total opioid-abstinent, up [illegible] was 61 percent. About one-fifth [illegible] sustained daily illicit opioid use for [illegible] after treatment. The remainder (18 percent) [illegible] or eliminated opioid use, but developed other [illegible] or prolonged incarceration.

[illegible] addicts, Dr. Simpson also found that [illegible] to be reasonably stable, such that abstinence [illegible] was predictive of abstinence at 12 years, while [illegible] continued daily use at 12 years. Among [illegible] frequent opioid use at 6 years, there was a [illegible] to daily use at year twelve.

[illegible] to treatment, Dr. Herbert Kleber and his [illegible] found that certain types of psychopathology were [illegible] with poorer treatment outcomes. In particular, [illegible] were predictive of [illegible] outcome, while [illegible] psychopathology [illegible].

As noted above, many of these [illegible] studies reflect well the [illegible] and results of a [illegible] population. However, the [illegible] diversity of drug use [illegible] that we will need to [illegible] diverse populations and treatment [illegible]. Recent research suggests that new [illegible] treatment [illegible] are being developed. These will [illegible] treatment systems. In turn new strategies for the longer term study of the course of drug use [illegible] with [illegible] will be developed.

Future Directions for Treatment Research

The [illegible] of treatment [illegible] in this country is only slightly [illegible] drug abuse research. A [illegible] review indicates that [illegible], being [illegible] with varying degrees of [illegible] (Gerstein, Hubbard, et al., [illegible] the [illegible] century patterns of use and abuse [illegible] have [illegible] evaluated [illegible] has been a [illegible] the predictive ability of [illegible] for the treatment strategies which have been developed. The [illegible] are [illegible] treatment for drug abuse the [illegible] currently [illegible].

Some of the advances in specific treatment techniques and in current thinking about the issues related to drug abuse treatment problems have been presented in volumes supported directly or indirectly by NIDA, including those listed below:

Progress in the Development of Cost-Effective Treatment for Drug Abuse
Research Monograph #58

Drug Abuse Treatment Evaluation: Strategies, Prospects and Progress
Research Monograph #51

Measurement in the Analysis and Treatment of Smoking Behavior
Research Monograph #48

Behavioral Intervention Techniques in Drug Abuse Treatment
Research Monograph #46

Cocaine: Pharmacology, Effects, and Treatment of Abuse
Research Monograph #50

Pharmacological Adjuncts in Smoking Cessation
Research Monograph #53

Commonalities in Substance Abuse and Habitual Behavior
Research Monograph In Press

These volumes, and others [illegible] in the literature, direct attention to [illegible] of treatment which should be addressed in future [illegible]. Two [illegible] which must be considered [illegible] and [illegible] of innovative treatment approaches [illegible] biological, pharmacological [illegible] interactions [illegible] (2) the [illegible] of changes in the drug [illegible] used, and the [illegible] and the evaluation. Specific [illegible] will include:

(i) evaluation of [illegible] and related biobehavioral strategies;

(ii) development of [illegible] durability of [illegible] effective but costly [illegible];

(iii) [illegible] associated with [illegible] step by step [illegible] readily [illegible].

[illegible]

INTRAMURAL RESEARCH PROGRAMS

Diagnostic Studies

Current efforts focus on the development and utilization of psychodiagnostic and electrophysiological measures in studies of adolescents and adult populations who are considered to be either drug dependent or at risk of becoming dependent. The first study in ARC history to focus on an adolescent population at high risk of developing drug related problems has been initiated. This study is designed to compare adolescents expelled from public schools for disciplinary reasons, such as fighting and drug or weapons violations, with students from similar backgrounds who appear resistant to such behavioral problems. This pilot study will serve as a basis for long term work into the neurophysiological, psychological, and social correlates of conduct disorder, in an effort to develop appropriate interventions and treatments for this high risk group. Studies of the adult drug dependent population focus on the relationship of drug abuse or dependence to psychiatric classification, emotional distress, aggression, and psychopathology.

Adolescent Study

Working relationships have been established with Baltimore City Public Schools and the Foundation for Youth Impact, a school for students who have been suspended or expelled. Most of the first 25 adolescents involved in our research come from those two sources. The State of Maryland, Department of Health and Mental Hygiene, Division of Juvenile Services is receptive to collaborating with us and the possibility of a joint study exists. The development of this effort was predicated on a budgetary level for FY 1986 that did not materialize. The degree to which the project can be sustained within existing ARC resources is yet to be determined.

Adult Studies

A screening battery of psychodiagnostic test has been implemented, to assess the psychiatric and emotional state of volunteers before they are actively involved in ARC studies. This battery provides protection to ARC research subjects while providing the data for studies into the relationship of psychopathology and drug dependence. Data obtained from these tests will be compared with populations who have not abused drugs to determine any important correlates or psychological or social markers for substance abuse. Two specific examples are given below.

Electrophysiological Correlates of Aggression and Psychopathology

Evoked potential measures of amplitude and latency are significantly associated with established measures of aggression and psychopathology. Fifty-one ward subjects admitted to the ARC for various ongoing projects have been tested for psychiatric diagnoses, personality disturbances, alcohol and drug use, and other behavioral disorders. Measures from these test batteries are compared with results of evoked potential measures of amplitude and latency. To date, the data indicates that subjects with more severe psychiatric or personality disturbances have amplitude and latency features which deviate significantly from the norm. Additional tests will be employed to determine whether these deviancies relate to histories of various types of substance abuse and whether behavioral observations conducted under laboratory proceedings also correlate.

Alcohol-Related Behavior Questionnaire

Adults with a history of usual to heavy alcohol consumption were administered the Alcohol-Related Behavior Questionnaire (ARBQ) in addition to control samples of normals. The ARBQ was designed by the ARC to assess behaviors associated with three simulated conditions of non-drinking, usual drinking, and heavy drinking. Five scales reflecting behavioral disorders commonly associated with drinking were constructed. Results indicate that the ARBQ reliably discriminated problem drinkers from non-problem drinkers and between psychiatric classifications. Several ARBQ scales were significantly related to established measures of behavioral disorders, particularly with respect to aggression, further validating the device. These findings confirm the need for such a test and its ability to advance the study of alcohol-related behavioral disorders and aggression. A study to obtain data from normals, consisting of workers and students, is underway and will enhance the meaning of data previously collected from ward subjects. Current research efforts focus on the development and utilization of psychodiagnostic and electrical measures in studies of adolescents and adult populations who are considered to be either drug dependent or at risk of becoming dependent.

V. UNDERSTANDING THE MOLECULAR AND CELLULAR ACTIONS OF DRUGS

At the most basic level, drugs produce their effects by altering the activity of individual cells. They may, for example, mimic naturally occurring neurotransmitters, stimulating or inhibiting the transmission of signals in the central nervous system, and affect its sensory function. Opiates, for example, mimic the actions of natural ocurring opioid peptides and inhibit the transmission of pain signals. Drugs may also, by a variety of mechanisms, alter the functions of cells throughout the body. For example, cigarette smoking is known to increase the risk of lung cancer and heart disease, the use of opiates leads to cell adaptation which is reflected in tolerance and dependence to opiates, and methamphetamine use can result in the degeneration of dopaminergic terminals through the production of a neurotoxin.

Because understanding the nature of these effects is of such fundamental importance in understanding the causes and consequences of drug abuse, research in this area has always held a high priority at NIDA. It is also an area where we have had our most notable successes, for it was largely through the work of NIDA grantees that the existence of opiate receptors and endogenous opioids was demonstrated. These proved to be seminal discoveries, not only to the area of drug abuse, but in the neuro and biomedical sciences as a whole.

Preclinical research intended to increase our understanding of the molecular and cellular actions of drugs includes: 1) investigations of the molecular structure of endogenous and exogenous substances; 2) studies of the pharmacokinetics and pharmacodynamics of drugs; 3) studies of their pharmacologic properties including searches for receptors that may be involved in drug abuse; 4) investigations of endogenous neurotransmitters and neurohormones - including studies of their distribution and function, the means by which they are produced and inactivated, and their genetic regulation; 5) searches for new endogenous substances that may be involved in the abuse of non-opiate drugs; and, 6) investigations of intra and inter-cellular processes-- including studies of events within the cell stimulated by the activation of a receptor and how changes in the inter-cellular environment affect the activity of a cell.

EXTRAMURAL RESEARCH PROGRAMS

Given the tremendous increase in cocaine use over the past decade and the continued widespread abuse of marihuana and opiates, it is not surprising that NIDA researchers have continued to develop knowledge about the action of these substances at the most basic level. That NIDA supported investigators can look with some pride at their accomplishments in this area is strengthened by the recent progress in our preclinical program.

The Three Families of Opioid Peptides

It is now established that all of the identified opioid peptides, also referred to as endorphins, are derived from three different precursor proteins. This processing takes place through the action of enzymes which cleve the larger molecule at specific sites and often involves several steps as the orginial precursor peptide is broken into progressively smaller fragments. Not only do the three opioid peptide families have separate biochemical synthetic processes, but they also have distinct neuronal pathways. Beta-endorphin, the active end product in the processing of proopiomelanocortin (POMC), has a high affinity for mu and delta sites, but less affinity, if any at all, for kappa sites. Met enkephalin, which is the end product in the processing of the precursor protein proenkephalin A, and [Leu] enkephalin in proenkephalin A and B, seem to possess a preferential affinity for the delta receptor. However, many of the intermediate peptides containing these two pentapeptides also have significant opioid-like activity, especially for the kappa receptor. Moreover, a single precursor peptide may generate several fragments with different receptor selectivities, and the selectivity may continue to change as the processing continues. This suggests that the processing enzymes might play a key role in determining the relative receptor selectivity of the processed peptides. For example, the mu receptor has been found to be involved in analgesia within the CNS, delta receptors act locally in the intestine to control secretion, and both mu and delta receptors are involved in bowel function.

In view of the above considerations, it is clear that systematic study of the pharmacology of the endogenous opioid peptide is needed. It is essential not only to identify the type of receptors activated by each native ligand but also to determine their pharmacologic profile. The information derived should cast light on their physiological functions and possible pathological roles, as well as on approaches that might be used to develop beneficial therapeutic agents.

Discovery of a New Processing Enzyme

Researchers at Johns Hopkins University (Dr. Mains and Eipper) have recently discovered an important prohormone post-translational processing enzyme, peptidyl-glycine alpha-amidating monooxygenase (PAM). PAM converts many small peptides with a carboxyl terminal glycine residue into alpha-amidated product peptides. Probably over half of all known bioactive peptides have an alpha-amidated COOH-terminus, and for most of the peptides the presence of the alpha-amide group is required for full biological activity.

The tissue distribution of PAM-like enzymatic activity capable of converting ^{125}I-D-Tyr-Val-Gly into ^{125}I-D-Tyr-Val-NH_2 has been determined. In adult male rats, the highest concentrations of activity are found in the anterior and neurointermediate lobes of the pituitary. Lower concentrations of activity are found in the hypothalamus, submaxillary glands and in the rest of the brain. Enzyme activity is also easily assayed in serum. Taking into account the mass of each tissue, the submaxillary glands and the brain are the major tissue sources of enzymatic activity, although serum contains more enzymatic activity than is found in the pituitary gland. In all tissues and in serum, enzyme activity is stimulated by the addition of copper sulfate and ascorbate and is dependent on molecular oxygen. This activity is therefore referred to as peptidyl glycine a-amidating monooxygenase or PAM activity.

Peptidyl glycine a-amidating monooxygenase (PAM) activity is being purified from frozen bovine neurointermediate pituitaries. The properties of the highly purified enzyme are not significantly different from those of the enzyme assayed in crude extracts (Km; dependence on copper, ascorbate, and molecular oxygen). Forms of PAM activity separable by ion exchange chromatography have a different pH, ranging from pH 7 to pH 9.

The factors controlling levels of PAM activity in its major tissue sources in the adult male rat were investigated by carrying out a variety of endrocrine, pharmacological and dietary manipulations. PAM activity in the anterior pituitary was increased following adrenalectomy or castration, and decreased following thyroidectory or treatment with haloperidol. Chronic dietary copper deficiency resulted in increased PAM activity in homogenates of anterior pituitary and submaxillary gland assayed under optimized conditions.

PAM activity is easily detectable in human plasma, cerebrospinal fluid (CSF), and various tissues. In human tissue and serum, PAM activity is dependent on copper ions, molecular oxygen, and ascorbate, and has kinetic and physical properties very similar to those of PAM from bovine and murine samples. In man, PAM activity is high in pituitary, brain, and tumors producing substantial amounts of alpha-amidated peptides. Relative to adult levels, plasma PAM is elevated in hypothyroid patients and in young children. PAM activity is elevated in plasma from patients with untreated Wilson's disease, a disease of copper metabolism in which serum copper levels are high. There is a readily detectable amount of PAM activity in CSF, but the correlation of CSF PAM activity and various physiological states is not yet complete.

Other Enzymes Involved in the Regulation of Opioids

The processing of endogenous opioids not only includes their synthesis but also their inactivation presumably through degradation. The peptide studied most is the 5 amino acid enkephalin [tyr-gly-gly-phe-(leu or met)]. It can be degraded by an aminopeptidase (removes N-terminal tyrosine), enkephalinase or angiotensin converting enzyme (which cleaves the gly-phe-bond) or dipeptidyl aminopeptidase (which cleaves the gly-gly bond). Most work centers on the enkephalinase which has been isolated and characterized. There is controversy as to whether it plays a key role in terminating enkephalin action because of its widespread distribution, regulation by inhibitors, and variable levels of activity.

The preparation of monoclonal antibodies against the purified enzyme should clarify its role in neuronal functions - whether it be at the synapse or some other site in the cell.

The aminopeptidase enzyme has been associated with cell changes and may or may not be related to analgesic actions. As this latter enzyme may be involved in cell development, more attention has been turned towards the third enzyme (the aminopeptidase removing the tyr group) and future efforts will concentrate on this system.

Opiate Receptors

Ever since the discovery of enkephalins and beta-endorphin, the role of the opiate receptor has received considerable attention. A number of receptor subtypes have been identified but controversies exist in assigning functional significance to any particular type; there is even question of whether or not the various subtypes are just different conformation of the same receptor entity. Definite clarification of these questions can only be expected upon the isolation of the receptor(s) in pure form. With NIDA support, several prominent groups have been working to isolate and characterize the opiate receptor(s). Although many partially purified and solubilized receptor preparations have emerged, only during the past year has an active and nearly homogenous purified "receptor" been identified. Most likely this "opiate receptor" will be a lipoprotein with a molecular weight around [illegible] daltons. Other higher molecular weight receptors have been isolated by Drs. Simon, [illegible], and [illegible], as well as those of [illegible] also identified by Dr. [illegible]. Whether this, or a similar lipoprotein, binds all the various types of ligands (mu, delta, kappa) is presently unknown. Most preparations bind mu ligands since the design of isolation centered on this group of compounds. Some degree of delta and/or kappa binding exists according to which laboratory preparation is being tested.

Utilizing a different approach, some investigators have prepared antibodies to segments of the "opiate receptor" or to partially purified preparations. Recent findings by [illegible] show that monoclonal antibodies (and their corresponding Fab fragments) are most effective against beta-endorphin but also compete with mu and delta ligand binding. Another polyclonal antibody is more specifically directed against mu ligands rather than delta or kappa ligands according to studies conducted by Dr. Zukin. The comparatively weak action of kappa ligands on these antigen/receptor preparations, in contrast to their [illegible] binding to other tissue preparations, indicates that another entity involving the kappa actions is yet to be identified.

Electrophysiologic studies deal with the types of receptors and their actions in various [illegible] systems, e.g. the brain, spinal cord, intestines and others. For instance, mu-like compounds have been considered as analgesics in the CNS whereas, more recently, delta-like compounds have been shown to act locally on intestinal mucosa to alter secretion. Antitransit effects are regulated by mu and delta compounds, locally, but only by mu compounds in the CNS. Thus, various actions as well as the region of regulation are being assigned to different opioid receptors.

Other recent studies on isolated cell cultures indicate that only one type of receptor is located on any one neuron and that different receptors may regulate different cell functions. For example, McDonald has demonstrated that mu and delta ligands act to regulate potassium ion flow through calcium dependent potassium channels. However, kappa ligands appear to act on voltage dependent calcium channels. This finding suggests that there may be at least two different cellular functions for these various opioid receptor types.

Still other investigators continue to probe the mechanism whereby opiates exert their effects. Primary attention continues to center on the adenyl cyclase and its coupled modulators - including the GTPase system. Presently, opiates act on what is called the Gi, or Ni, unit of the adenyl cyclase to down-regulate or shut off the system. Most neurotransmitters exert their action on another subunit (Gs or Ns) to up-regulate or enhance adenyl cyclase action. Some investigations are determining how this action might be linked to ion channel transport in neurons. More recently it was shown that treatment of spinal cord neurons with opiates alters both the opiate and serotonin actions. Instead of producing opposing actions, these two different drugs produced a similar result - a diminished inhibitory action on adenyl cyclase. This shows that there may be more than one type of neuronal coupling of the adenyl cyclase and the regulatory subunits.

From these studies, it now appears that however the different opioid systems (receptors) are constructed, they assume different roles in different cells in different parts of the nervous system, to regulate, along with various neurotransmitters, the cellular and hence the physiologic functions of the body.

Cannabinoid Binding Sites

Delta-9-THC, the major active component of marihuana and many of its analogs, produces a characteristic psychotropic response in humans and recognizable behavioral alterations in lower animals. The psychotropic effects of cannabinoids very likely involve interactions with specific receptor sites. Cannabinoids such as delta-9-THC act at low doses, their psychotropic effects exhibit stereospecificity and small chemical changes produce marked alterations in pharmacologic actions. Studies of $[^3H]$-cannabinoid binding to brain tissue, however, have failed to reveal stereospecific and saturable binding sites with high affinities. The reason for this may be the extreme hydrophobicity of THC which may interfere with specific receptor binding due to the extensive partitioning of THC into the lipid of brain membranes. One way to overcome this problem is by synthesizing a more water soluble quaternary ammonium cannabinoid. Under NIDA's drug supply contract, the Research Triangle Institute synthesized trimethyl ammonium delta-8-THC (TMA), a water-soluble derivative of THC. Researchers at Johns Hopkins University demonstrated the high-affinity binding of ^{3}H-TMA to membranes of brain and other tissue, compared the potencies of numerous cannabinoids at these binding sites and characterized ^{3}H-TMA binding to solubilized membrane preparations. Their major finding was that saturable binding of ^{3}H-TMA can be demonstrated in brain membranes. The binding sites have high affinity for delta-9-THC in the range of serum concentrations associated with threshold psychotropic doses, and resembles the affinity of a number of potent psychotropic agents for their pharmacologically relevant receptors. By contrast, the maximum number of ^{3}H-TMA binding sites are much greater than values for most drug and neurotransmitter receptors. Some of the cannabinoid specificity of the ^{3}H-TMA binding sites fits with in vivo affinity for binding sites, and may not mediate the major psychoactive effects of marihuana in humans, but they may be responsible for some other pharmacologic effects of THC.

This is the first demonstration of the existence, in the brain, of high affinity binding sites for components of marihuana, and it opens the way for further scientific studies of the pharmacology of marihuana to elucidate the mechanisms of action of its active ingredients.

INTRAMURAL RESEARCH PROGRAMS

The Neuropsychopharmacology Laboratory at the ARC conducts research to better understand the mechanisms of action and neuroanatomical sites of action of psychoactive substances with an emphasis on drugs of abuse. Results of these studies will provide systematic assessments of the neuropharmacological and neuroanatomical substrates which mediate the reinforcing, dependence-producing, and other properties of drugs of abuse. Current efforts fall into four categories of studies: (1) studies of the neural substrates of reinforcement; (2) studies of the mechanism of action of sedative-hypnotics; (3) studies of the mechanism of action of putative kappa and sigma receptor agonists; and, (4) studies of the mechanism of action of peptides and endogenous substances.

The majority of studies are conducted in laboratory animals, although some involve human subjects in collaboration with the ARC's Clinical Branch.

Cocaine Receptors

Cocaine presumably exerts its psychotropic effects through specific receptors in the brain. While two, and possibly more, binding sites or receptors for cocaine have been found in the brain. It is not completely clear which of these, or whether all of them, are in fact involved in producing cocaine's euphorigenic effects which leads to its abuse. Identifying the relevant receptors for cocaine is worthwhile, not only from the point of view of understanding its mechanism of action, but also because it could lead to the development of drugs which might block the action of cocaine.

In addition, while it is important to identify a receptor in the brain, it is only by knowing the distribution of this receptor that we can fully understand how the drug exerts its effects. There are many neuronal circuits, and receptors for drugs are often highly concentrated in only some of the circuits. A powerful approach to identifying brain regions involved in the action of cocaine is called receptor mapping. The ARC's laboratory is expert in these techniques and has begun localizing receptors for cocaine in various brain regions by [illegible] techniques. Initial results indicate that such studies can reveal [illegible] at least one of the cocaine receptors [illegible]. Further efforts will continue these mapping studies [illegible]. Studies [illegible] have been conducted at the ARC.

Finally, a series of experiments [illegible] that the endogenous substance [illegible] drug taking behavior [illegible]. The reinforcing properties of drugs appear to be [illegible] by stress and [illegible]. Of particular interest is determining the neural substrates which mediate the reinforcing properties of cocaine and other [illegible] in conjunction with stress, [illegible] and conditioning.

Sedative-Hypnotics, Hallucinogens, and PCP

Studies on the mechanism of action of sedative-hypnotics have [illegible] in vitro [illegible]. Attempts to [illegible] have been [illegible] effects of benzodiazepines. These [illegible] the neural substrates of action and the [illegible].

Studies of [illegible] phencyclidine and [illegible]. Additional studies have indicated the presence of [illegible].

Further studies have shown that the benzodiazepine [illegible] and physical dependence [illegible] are mediated by distinctive [illegible]. These [illegible] a better understanding of the neural [illegible] which mediate anxiety and the role of anxiety in the initiation of drug taking behavior. [illegible] in the development of therapeutically useful anxiolytics with a lower dependence potential. Another important area of interest is to delineate the pharmacologic role of sigma receptor subtypes in mediating the psychotomimetic and reinforcing properties of benzomorphan opioids and phencyclidine.

New Directions

Studies planned will investigate the neuroanatomical and neuropharmacological substrates mediating the reinforcing properties of cocaine and other psychomotor stimulants, including the endogenous transmitters involved. In collaboration with the ARC's Neuroscience Branch, metabolic mapping studies will correlate changes in cerebral metabolic activity with changes in drug-taking behavior. Additional studies will continue to delineate the mechanisms and sites of action of benzodiazepines in producing anxiolytic and sedative effects, as well as physical dependence. Further studies will continue to delineate the subtypes of sigma receptors and their role in producing euphoria or dysphoria and in maintaining drug-taking behavior.

Studies with multiple opioid agonists and antagonists will incorporate recently developed opioids and opioid-like compounds to further assess the role of distinct drug receptor populations in the mediation of the responses to these drugs.

VI. UNDERSTANDING THE ACTIONS OF DRUGS ON THE CENTRAL NERVOUS SYSTEM

While understanding how drugs affect individual cells is a basic step in drug abuse research, it has become increasingly clear over the last ten years that research at this level does not lead directly to an understanding of their effects on behavior. For example, in every case that has been studied, from the spinal cord to the forebrain, opiates have been shown to decrease the activity of neurons. This finding, while important, does not itself explain how opiates produced such diverse effects as euphoria, analgesia, and decreased breathing rates and body temperatures. To satisfactorily explain these phenomena, one must go beyond the study of individual cells to studies of systems or circuits of cells within the central nervous system. While research in this area has been conducted for some time, it was not until relatively recently that a combination of theoretical and technological advances opened the way to more rapid progress. For example, one of the most important findings of the last several years is the dissociation of two of the major effects of narcotics: euphoria and dependence. These effects result from actions of the drug at two anatomical and functionally distinct sites within the brain. Furthermore, the site at which narcotics produce euphoria is identical to that responsible for cocaine-induced euphoria. These findings have revolutionized our understanding of drug abuse in a fundamental manner. First, the desirability of a drug is independent of the physical dependence liability it presents. In addition, the distinction between these effects explains why drugs from a variety of classes share a common mechanism which is responsible for the euphorigenic action.

Current research in this area involves: 1) studies of the effects of drugs on behavior and how these effects may be influenced by environmental factors; 2) investigations of brain circuitry involved in reward and how it is affected by drugs; 3) investigations of cognitive function and how it is affected by various drugs; 4) investigations of environmental influences on brain function; and, 5) studies to determine the nature and extent of structural changes in the brain resulting from drug use.

Recent progress toward gaining a better understanding of the actions of drugs on the central nervous system has occurred as a result of studies of amphetamines, hallucinogens, and other drugs. Findings and directions for further study are outlined below.

EXTRAMURAL RESEARCH PROGRAMS

Brain Reward System

A growing body of knowledge has accumulated to form a powerful model to understand and predict drug seeking behavior: drugs are abused because they directly activate the reward circuitry of the brain through neuropharmacological mechanisms. Actually, it has been a well-known finding for some time that experimental animals will work for electrical stimulation of certain neural pathways in the brain. This finding has given rise to the concept that there are circuits in the brain which are responsible for pleasure. Presumably any pleasurable stimulus derives its rewarding value from the activation of these specific "brain reward" circuits. Consistent with this idea is the finding that animals will work for microinjections of drugs, including cocaine, directly into specific regions of the brain that are part of a pleasure circuit. Animals will also work for microinjections of morphine into a related part of this circuit. Thus, the anatomical basis of "reward" is the same for a variety of drug classes. Hence, the rewarding impact of various drug classes can be compared leading to the recent discovery that cocaine is just a rewarding as heroin. In fact, cocaine may possibly be even more dangerous than opiates when considering that animals will self-administer cocaine to the point of death whereas they limit their intake of opiates and remain relatively healthy.

During 1985, several findings were reported which are relevant to how drugs act on the brain reward system. The electrophysiological characteristics of cocaine in reward circuits were shown to be directly related to its ability to block dopamine reuptake, and not to its ability to produce membrane effects like those responsible for its potent anesthesic actions. Second, opiates and cocaine were shown to produce the same biochemical response in the ventral tegmental area (VTA). The VTA is a nucleus of dopaminergic cell bodies which supply dopaminergic terminals to the cortex and limbic systems and forms the major neuronal basis of the "reward system." In this system, both opiates and stimulants increase dopamine turnover in the VTA and its projection regions. Third, the brain's reward system was shown to be lateralized. Data showed that the degree of cerebral dominance is an important determinant of inter-individual differences in sensitivity to reinforcement from either cocaine, amphetamine, or morphine.

Another important outcome of this work is that the brain sites responsible for the rewarding action of drugs (psychological addiction) have been dissociated from those responsible for physical dependence (physical addiction).

Other recent findings suggest that cerebral laterality (the relative dominance of one side of the brain), and sex, may determine an individual's potential to abuse drugs. In one study using intracranial self-administration (ICSS) to elevate the reinforcing action of a drug, the action of cocaine, amphetamine, and morphine depended on the hemisphere where it was administered, and the sex of the subject. As a result of studies to focus on this finding, it was discovered that sex differences play a role in the drug response. In females, cocaine potentiated the laterality while in males the opposite effect was found. The differences in drug action between sexes appeared to be due to an inherent increased terminal density of receptor sites in females and more reuptake sites per neuron in males.

Finally, the model for the brain's reward center involved in drug seeking behavior has predictive validity. A comparison of the reinforcing action of a variety of drugs, with their ability to lower the threshold for reward following brain stimulation of positive sites, shows that all drugs with high abuse potential, and which have been tested, fall within this rule. Not only does this help us to understand why drugs are abused, the model may also lead to vastly improved methods for evaluation of the abuse liability of drugs.

CNS Actions Of Cocaine

During the past year, the basis for at least two actions of cocaine were discovered. Though the findings are still preliminary, it now appears that, in one group of neurons, the effect of cocaine is to block the chloride ion channel that is opened by the inhibitory transmitter GABA. The GABA-induced flow of chloride out of a neuron reduces the activity of that neuron. Cocaine, by blocking this action, causes the neuron to remain in an excited state. Because reduction in GABA action has been linked with the development of epileptic seizures, it is possible that the ability of cocaine to block GABA action may underlie its epileptogenic actions. In other neurons, which receive input from norepinephrine-containing nerve fibers, cocaine has been shown to decrease cellular activity. Since norepinephrine is known to inhibit these neurons, this action of cocaine is probably due to its known ability to block the reuptake of norepinephrine, thus prolonging its inhibitory effects, rather than to a direct action of cocaine on the neurons under study.

The effects of amphetamine and cocaine on the neural circuits underlying sensorimotor integration are being studied in animals performing specific tasks in response to sensory cues. One kind of neuron in the cerebellum is inhibited by direct application of either amphetamine or cocaine, an effect that may explain the increased ability to concentrate that is reported by stimulant users during the acute phase of intoxication. Of equal note is the development of a technique to apply drugs directly to single neurons in awake, behaving animals. As mentioned, this is a major technological development that has significantly enhanced our ability to study the actions of drugs.

Amphetamine and chemically related analogs are commonly abused by users because of their stimulant and euphorigenic properties. Tolerance to the psychomotor stimulant effects of amphetamine and other chemically related analogs develops very rapidly. While a dose of 2.5 mg to 15 mg/day may be prescribed for medical purposes, chronic amphetamine users have been known to consume as much as 1,500 mg a day. The abuse of amphetamines can lead to a series of adverse effects on the nervous system, the seriousness of which depends upon the duration and quantity of amphetamines abused.

Synthetic Analogs of Amphetamine and Methamphetamine

Several dozen analogs of these stimulants are known, or theoretically likely, to possess hallucinogenic properties as well. The recent appearance of several synthetic analogs, or so-called "designer drugs," with these combined effects has prompted renewed research interest in this class of drugs. Through NIDA sponsored research it has been discovered that neurotoxin formation from the brain's own neurotransmitter is induced by various amphetamine analogs such as MDA and methamphetamine.

Recently, NIDA grantees at the University of Chicago, Drs. Lewis S. Seiden, and Charles Schuster and their associates, demonstrated that methamphetamine and +-3,4-methylenedioxyamphetamine (MDA) are toxic to brain serotonergic neurons. Administration of these drugs, and some related compounds including fenfluramine, to rats produces long-lasting depletions of serotonin (5-HT) and 5-hydroxyindoleacetic acid (5-HIAA), and a reduction in the number of high affinity membrane transport sites for 5-HT. In the case of MDA, these deficits have been shown to result from 5-HT nerve terminal degeneration. Methamphetamine and related compounds also destroy dopaminergic nerve terminals. Previously, Seiden and Schuster and their associates had demonstrated that 6-hydroxydopamine (6-OHDA), a neurotoxin selective for catecholamine-containing neurons, is formed in the striatum of the rat following a single large injection of methamphetamine. The methamphetamine induced formation of 6-OHDA is blocked by prior administration of alpha-methyl-p-tyrosine, a dopamine (DA) synthesis inhibitor. It is hypothesized that 6-OHDA is produced from DA in the striatum and, once formed, mediates the toxic effects of methamphetamine on dopaminergic neurons. More recently, Seiden and colleagues have found that methamphetamine also induces the production of another neurotoxin, 5,6-dihydroxytryptamine (5,6-DHT), in the rat hippocampus. Their paper appears to be the first report of the endogenous formation of a serotonergic neurotoxin. This study has demonstrated that the amount of 5,6-DHT produced is probably sufficient to cause the long-term 5-HT depletions observed after methamphetamine administration. These observations raise important questions as to whether endogenous neurotoxins are formed normally in the human brain in potentially toxic amounts. Also, it raises the issue of whether these toxins have any role in the causation of the CNS adverse effects resulting from the abuse of amphetamine and related drugs.

CNS Actions of Hallucinogens

Great interest was generated in the research community during the 1960's and 1970's concerning studies on hallucinogenic drugs. NIDA funded a major portion of this work but the research potential in this area was only beginning to be exploited when different priorities shifted interest to other areas.

New initiatives are planned to stimulate research in this potentially fruitful research area. The development of new information on structure-activity relationships in the substituted amphetamine series are planned. Many of the compounds in this general class have potent psychomimetic activity, frequently making them candidates for abuse, but also in many cases offering the possibility of useful therapeutic application.

Because of the complex neurological action of hallucinogenic drugs and their abuse potential, development of these drugs as therapeutic agents has been slow. Nevertheless, it is this complexity of action which makes them interesting research subjects. Much can be learned about central neurological function in the human brain by the application of basic structure-activity studies on drugs, such as the substituted amphetamines, which mimic mental disease states or alter normal ones.

The development of a strong basic research program in this area will provide information necessary for a better understanding of basic neurological functions as well as the basic mechanisms of hallucinogenic drug abuse. At the same time these studies may allow the development of therapeutic drugs which can be used for treatment of drug abuse and, more importantly, for the treatment of certain aspects of mental illness.

Concern and interest in research on hallucinogens increased sharply in 1985 due to the widespread use of MDMA, a drug with strong reinforcing characteristics that apparently shares hallucinatory and stimulant properties. Despite being placed under control in July 1985, another analog, [methylenedioxy-N-ethyl-amphetamine (MDE)], appeared in illicit drug distribution which was in heavy use by October 1985. It is claimed that these substituted methamphetamine compounds have great therapeutic potential in psychotherapy, but as was discussed earlier, developing data indicates they may be neurotoxic in humans. MDE has recently been synthesized under NIDA's drug supply program and is currently undergoing abuse liability and neurotoxicity tests.

Adaptive Responses to Pain and Stress

Much evidence now indicates the existence of multiple endogenous analgesia systems, only some of which rely on opioid peptides. Given that such systems exist, a natural question is to determine when are they employed. Pain can be a vital warning signal and its inhibition ought not to be trivially invoked. During times of extreme stress, however, pain inhibition may be the most adaptive coping response. Since 1976, many investigators have shown that exposure to stress can cause analgesia in laboratory animals. In some cases stress analgesia appeared opioid mediated, in others not. Because of the differences in experimental procedures among laboratories, integration of this body of work has been difficult. It had been demonstrated that a single stressor, such as footshock under certain conditions, could elicit either an opioid or a nonopioid form of analgesia depending on the parameters of its application. Intermittent footshock caused analgesia that, according to several criteria, appeared opioid mediated. Continuous footshock, by contrast, elicited an equipotent analgesia that was, by these same criteria, nonopioid. Thus, multiple endogenous pain-inhibitory systems exist and these can be selectively activated by stress.

The role of opioid peptides in the regulation of the organism's adaptive response to chronic stress had been extensively investigated by researchers at the University of Michigan. In male rats, they have demonstrated that the history of chronic stress does not affect the subsequent glucocorticoid rise to a new stress administered more than 8 hours after a previous stress. In addition, the resting corticosteroid levels are often normal in chronically stressed rats. However, when they directly examined anterior lobe pituitary content of ACTH and related peptides, there was a twofold increase in these peptides with chronic stress. This elevation occurs in both final products (ACTH, Beta-endorphin and ß-LPH) as well as precursors and intermediates. Such an increase in POMC derived peptides stores, and in releasability of these peptides, could be an adaptive mechanism to maintain both high circulating levels and adequate stores of ACTH during a situation of high demand (severe stress). That is, in a chronically stressed rat, the anterior pituitary can release the same amount of ACTH with less depletion of ACTH stores. The increased releasability would assure that the chronically stressed organism is able to meet the demand for ACTH with greater ease than a naive animal.

Other investigators suggest a complex interaction of drugs in stress. Opioids are not the only drugs to act on stress, but recent observations indicate that nicotine also acts to reduce stress. Nicotine may act through the opioid system, as they also modulate the release of ACTH and prolactin, or through other related systems.

There have been changes in the past 15 to 20 years in new drug development and in psychometric approaches to the evaluation of pain, mood and psychomotor function. These changes strongly suggest that we review and modify methods for the clinical evaluation of analgesic treatments. For example: there are now drugs, considered aspirin-like in many ways, which have the analgesic effectiveness of narcotics commonly used in the treatment of moderate to severe pain. Among these new drug classes are: 1) subclasses of opioids (e.g., partial agonists, mixed agonist-antagonists, receptor-selective agonists) with limited abuse liability, possessing pharmacologic profiles quite different than that of morphine; and, 2) centrally-acting analgesics which do not bind to the opiate receptor. It has become increasingly difficult to classify many new analgesics simply as "mild" or "strong," or to recommend that they be used for either "mild to moderate" or "moderate to severe" pain. On the other hand, considerable progress has occurred in characterizing various pain syndromes in terms of their differing qualities, and in demonstrating that all pain is not the same, differing only in intensity. Thus, a developing area of interest is the extent to which these new analgesics show differential effectiveness for specific pain syndromes.

One major long-term effort is focused on two central issues: (1) the therapeutic merits and pharmacokinetic properties of specific analgesic drugs, and (2) the development of more precise methods for determining the comparative advantages and disadvantages of new and currently available strong analgesics, particularly in relation to their pain relief and mood altering effects. Parts of several other NIDA grants look at the influence of stress on the analgesic effects of morphine and methadone, seeking to determine how stress enhances their analgesic effects.

Major accomplishments include the assay of a number of different drugs including levo-alpha acetylmethadol (LAAM), meptazinol, fenoprofen and flurbiprofen. LAAM, a long-acting methadone used to suppress drug seeking behavior in addicts, may also be of great value in pain management because of its extended duration of action. Thus far, in studies comparing LAAM with intramuscular (IM) administration of regular methadone, patients experiencing chronic pain due to cancer report no differences in the side effects produced by either drug.

Meptazinol is an agonist-antagonist opioid analgesic reported to be unique in its relative selectivity for mu$_1$ (high affinity) opioid receptors as determined in rat brain binding assays. The high affinity mu$_1$ receptors are felt to be associated with analgesia, whereas in an animal model the low affinity receptors (mu$_2$) have been implicated in respiratory depression and toxicity. Reports from studies in man, in a variety of clinical settings, has showed the drug to be a well tolerated analgesic with little or no adverse respiratory or cardiovascular effects. Meptazinol is shorter in duration of action but more rapidly effective as an analgesic in comparison to morphine. The drugs differed considerably, however, in terms of their other side effects. The major side effect following morphine was drowsiness, whereas meptazinol was associated with a relatively high frequency of nausea, sweating, dizziness, vomiting and a number of dysphoric reactions. Many of the latter, in particular the profuse sweating and dysphoria, developed suddenly within 10 minutes of the IM injection and had largely dissipated within the first hour. There were no associated cardiovascular, respiratory of pupillary changes and the symptom complex did not resemble precipitated withdrawal--nor were any of these patients suspected of having a prior physical dependence to narcotics. Other data from this study showed consistent dose related mood improvement following morphine and either neutral or dose related negative effects on mood following meptazinol. Even though meptazinol itself may not represent the best alternative to opiates, information gained from these studies will further the search for effective analgesics that have low abuse potential.

One common cause of pain is inflammation, which is often treated with corticosteroid medications which have deleterious long term side effects and significant abuse potential. Thus, the development of effective nonsteroidal anti-inflammatory drugs (NSAIDs) would be an important addition to the pain treatment armamentarium. In this context some NSAIDS have been demonstrated to be as effective as morphine in suppressing postoperative pain due to cancer. Thus far, the new NSAIDS are found to be more effective analgesics in treating pain which has been customarily treated only with opioid analgesics. That NSAIDS are as capable as opiates in supressing post-operative pain is significant given their relatively low abuse potential.

Additional areas of interest include: 1) more precise prediction of which drugs provide effective analgesia yet pose lower abuse liability for particular individual's; 2) application of the principles of behavioral analysis to schedules and routes of administration so as to maximize analgesic effectiveness and minimize abuse potential; and, 3) methods for promoting rational use of analgesic therapeutic strategies by physicians.

Opioid Peptides in Neural Injury

Several lines of evidence have suggested a role for endogenous opioids, and especially peptides derived from pro-dynorphin, in the motor paralysis observed following severe spinal cord injury. The concentration of dynorphin A immunoreactivity (Dyn A-ir) found in the spinal cord is fairly high relative to other CNS regions. Intrathecal injections of Dyn A and related peptides produce severe hindlimb paralysis in rats . Neurologic recovery following spinal cord injury is significantly improved if high doses of naloxone are administered either before or after the injury. The opioid antagonist, WIN 44,441, which has somewhat greater activity at kappa opioid receptors than naloxone, is more potent than naloxone in facilitating recovery following spinal injury. In a recent study it was found that severe spinal cord injury resulting in hindlimb paralysis twenty-four hours later was associated with a significant elevation of Dyn A-ir in the injured region, and also below the injury site. In contrast, spinal cord leu-enkephalin immunoreactivity was unchanged by the injury. Further experiments indicated that Dyn A biosynthesis in the neural soma may be accelerated following injury. Unpublished preliminary results showing that the tissue content of larger precursor forms of dynorphin are elevated after injury would be consistent with this interpretation. Overall, the results support the hypothesis that dynorphin may contribute to paralysis following spinal injury.

Dynorphin related peptides may also be involved in the pathophysiology of neurological deficit caused by cerebral ischemia (stroke). In humans, the opiate antagonist naloxone can reverse neurologic deficits secondary to cerebral ischemia, whereas morphine exacerbates them. The neurologic deficits produced by unilateral carotid ligation in gerbils can be reversed by intraperitoneal administration of naloxone. In baboons, naloxone partially reverses and morphine exacerbates, ischemic neurologic deficits resulting from focal cerebral ischemia produced by permanent unilateral occlusion of the internal carotid, posterior communicating, and proximal middle cerebral arteries.

In a series of experiments, performed at the University of California in San Francisco, investigators examined the effects of both acute and long-term continuous administration of six different opioid compounds--naloxone, naltrexone, diprenorphine, leucine enkephalin, dynorphin 1-13, and dynorphin 3-13--on neurologic function, survival, and infarct size in a feline model of acute focal cerebral ischemia. These effects were compared to those in a control group of cats, matched to the experimental group for age, sex, and weight, that was treated similarly with normal saline.

Naloxone, naltrexone, and dynorphin 1-13 significantly prolonged survival whereas the other drugs and saline had no effect. The infarcts involved the sensory and motor cortex, internal capsule, and caudate nucleus. The infarct size was not altered by any treatment administered, and there was remarkable similarity in the results among groups. These results provide further evidence of the possible involvement of endogenous opioid peptides in the pathophysiology of cerebral ischemia, and suggest that opiate antagonists may be useful in the treatment of focal ischemic neurologic deficits. The protective effect of dynorphin 1-13 against death from focal cerebral ischemia demonstrated in this study warrants further investigation.

Drug Abuse and the Immune System

Recently it has become clear that the immune system is subject to modulation by the central nervous system. There is an intimate regulatory feedback relationship between the two systems mediated by hormones such as ACTH, endorphins, enkephalins, and corticosteroids. Receptors have been identified for these hormones in the CNS, pituitary, as well as in the lymphocytes, and a number of abused drugs are known to bind to some of these receptors; thus an interaction between the two systems can be modulated by drug abuse.

The abused substances which have been mostly studied for their effects on the immune system are marihuana and the opiates. A large number of diverse studies have been performed to look at this effect of marihuana. Marihuana smoke and cannabinoids depress the immune system in animals probably by their effect on B-cells, and has been shown to increase susceptibility of guinea pigs to viral infections. Despite these findings in animals, results in studies of humans were inconclusive. With NIDA support, a comprehensive review of these various studies was performed in 1983 by Dr. Albert Munson at the Medical College of Virginia. The immunosuppressive effects of marihuana are not unexpected since the work of Burstein has shown that cannabinoids can affect the synthesis of prostaglandins, which have been themselves reported to inhibit immune responses. Part of this information is of a preliminary nature and so far there is little data on the effects of hallucinogens, stimulants and depressants on the immune system. Interactions of abused substances with other compounds, such as alcohol or therapeutic drugs, should also be investigated in view of their possible effect on the immunocompetence of the individual.

This type of research is of particular significance in view of reports that a significant portion (25 percent) of cases of Acquired Immuneodeficiency Syndrome (AIDS), reported to the Centers for Disease Control, involve intravenous drug abuse.

Dietary and Environmental Factors in Drug Abuse

The role of nutritional and environmental factors in the causation of tolerance and physical dependence will be an important new initiative. Current research on the effects of nutrition on CNS function has reached a stage where we can start to ask questions about the role of macro and micro nutrients on the modulation of those processes which are known to be involved in the causation of physical dependence. For example, one of the most important roles the nutrients play is the modulation of synthesis and release of monoaminergic neurotransmitters in the neuronal terminals of the brain. When the kinetics of the synthesis of a neurotransmitter is dependent upon the concentration of neurotransmitter precursor amino acids, as is the case with serotonin, the neurotransmitters mediated by these monoamines can be affected by the availability of their precursor amino acids. Since these precursors are supplied to the body via the diet, diet induced alterations in plasma composition of amino acids can affect the synthesis of these neurotransmitters. This latter effect may have important clinical implications. In experimental animals altered tryptophan availability results in a loss of physiological responses which often parallel an inferred change in serotonin in the CNS serotonergic neurons. The responses which are altered include response to pain, aggression, sleep, sexual behavior, startle response, blood pressure, growth hormone, prolactin, renin, Beta-endorphin and self-administration of amphetamine. Furthermore, several of the effects of drugs of abuse are manifested through their interaction with the functional state of the sympathetic nervous system. The latter is affected by cold exposure, fasting and dietary factors such as ingestion of fat and sucrose. Thus, the central and peripheral adrenergic systems appear to play a major role in opiate dependence and withdrawal in man and experimental animals. Biogenic amine levels have been measured in the brain and periphery in many studies to correlate particular neurotransmitters with opiate dependence and withdrawal. The most consistent correlation has been observed between withdrawal and catecholamine neurotransmitters in the brain and adrenals suggesting that NE plays an integral role in opiate withdrawal. This thinking has been further substantiated by other experimental approaches, e.g., the use of clonidine, an alpha-2 adrenergic receptor agonist. Clearly, physiological modulation of sympathetic nervous system by diet and other means could have important ramification for an understanding of the phenomena of tolerance, dependence and withdrawal.

Currently we have only one grant in this field. However, during the next two years, we plan to encourage investigators to study several new areas. These areas include study of the effects of various factors in the development of tolerance, physical dependence and self-administration of drugs. These factors include palatability of food, particularly sugar, dietary amino acid precursors of neurotransmitters and the role of autonomic nervous system, caffeine, dietary fat and protein, and environmental factors related to nutritional status, e.g., hibernation, regulation of caloric intake, etc. A technical review and an announcement in the NIH Guide for Research Grants and Contracts is also planned.

VII. UNDERSTANDING THE BEHAVIORAL EFFECTS OF DRUGS

One of the crucial steps in understanding how drugs affect the central nervous system is to determine precisely what their effects are on behavior. Because behavior is a manifestation of the functional activity of the central nervous system, the cumulative biochemical and physiological effects of drugs on the central nervous system can often only be understood by examining an organism's behavior in response to differing pharmacological and environmental variables. Basic laboratory research has developed techniques which allow precise measurements of subtle alterations in ongoing behavior. These methodological and technological advances have made possible a variety of basic and applied studies in both animals and humans.

For example, studies of the behavioral effects of administering drugs at various doses, at different intervals, and under diverse environmental conditions provide us with valuable information about the pharmacological properties of particular drugs. This information is in turn useful in studies seeking to determine how a drug acts in the central nervous system. In some cases investigations of drug effects occurring at very precise locations in the brain have made it possible to develop behavioral profiles useful in determining which drugs affect the same area of the brain.

This line of inquiry has also resulted in major advances in applied research on treatment and prevention. For example, studies of the reinforcing effects of drugs made possible the development of reliable methodologies for conducting abuse liability tests which predict the likelihood a substance may be abused. Research on the behavioral effects of tobacco and narcotics led to a much better understanding of why relapse rates for users of these drugs are so high and have fostered the development of programs designed to promote the retention of positive outcomes following treatment. Finally, studies measuring subtle changes in complex behaviors resulting from drug use have provided information now being used to assess the effects of drugs on performance in the workplace and other settings. All of these practical applications have resulted from our efforts to better understand the behavioral effects of drugs.

EXTRAMURAL RESEARCH PROGRAMS

Effects of Drugs on Performance

It is becoming increasingly clear that a variety of drugs of abuse are capable of altering human performance. Data from studies of accident victims indicate an unexpectedly high percentage of persons killed or injured in automobile accidents have self-administered psychoactive drugs, often in combination with alcohol. There is a growing body of evidence suggesting that automobile accidents may be due to impaired performance caused by drug use. Special concern has been expressed about marihuana use and driving, since such a large number of young people appear to drive under its influence. Also, in this context, the increasing use of cocaine, and its possible adverse effects on the skilled performance needed to operate an automobile, is a growing concern.

Studies on the drug effects on performance of skills necessary to fly a plane, drive an automobile or to operate machinery have focused on marihuana alone or in combination with alcohol, and on benzodiazepines alone or in combination with alcohol.

Research data on pharmacokinetics of delta-9-tetrahydrocannabinol (THC) and pharmacodynamics of the self-reported psychological high effect after smoking single marihuana cigarettes were analyzed and published in Clinical Pharmacology and Therapeutics by NIDA scientists Drs. Chiang and Barnett. The pharmacologic response to smoking a marihuana cigarette was correlated with the plasma THC levels via pharmacokinetic models and phase plots of effects versus concentrations. From this model, it was observed that the psychological high effect is directly related to mean THC plasma levels from approximately 1 hour through 4 hours after beginning to smoke a single marihuana cigarette. The psychological high effect was mathematically described through pharmacokinetic analysis of THC plasma levels.

NIDA grantees Drs. Yesavage and Hollister have studied the effects of marihuana smoking on the behavioral and cognitive performance of pilots using a flight simulator. Performance after smoking a single marihuana cigarette, with a THC concentration of less than 2 percent, showed decrimental effects for at least 4 hours, and evidence suggested a 24 hour "hang over" as well. Further research will continue to define the time period during which the performance is impaired and also to define the minimum biofluid drug levels at which the performance is affected.

Studies of the effect of marihuana alone or in combination with alcohol, and of diazepam alone or in combination with alcohol, have measured driving ability as performed in a laboratory. Driving performance was evaluated using a graphics display simulator with realistic car dynamics. Data on the effect of marihuana alone, and in combination with alcohol, on driving performance were analyzed by Dr. A. Smiley under a NIDA contract. Marihuana was found to significantly impair speed control, tracking and perceptual functions involving driving. Impairment increased with dose. The addition of alcohol at blood alcohol concentration levels of 0.08 percent showed trends (non-significant) toward worse performance on these measures.

From analysis of data on the effect of smoking marihuana on performance of laboratory tasks related to automobile driving, a publication by Drs. Barnett, Licko and Thompson in Psychopharmacology showed that decremental effects were likely to peak immediately after smoking with performance returning to normal in 2 to 8 hours, depending on the behavioral test being used. A positive correlation between impaired performance and the THC plasma levels for a period of up to 12 hours after smoking was also reported.

The effects of diazepam alone and in combination with alcohol on driving performance were also analyzed by Dr. Smiley. Diazepam was found to impair performance on a wide range of simulated driving tasks. Adding alcohol to diazepam further impaired performance on nearly every task measured. The few significant alcohol and diazepam interactions indicated that combined effects were essentially additive in the dose range studied.

During the last year, NIDA initiated a well controlled investigation of the psychological, behavioral, cognitive, and pharmacokinetic interactions of marihuana and diazepam, in combination with alcohol. The study, conducted by the Research Triangle Institute, used the Self Evaluation Driving Impairment (SEDIT) equipment to measure the performance of skills necessary to drive an automobile. Preliminary analysis of these data indicate no synergistic effects but confirm the clear additivity in impairment of performance found in earlier studies.

Productivity & Educational Achievement

In addition to the safety issues, an important area of research is the determination of which drugs of abuse affect learning, motivation, and productivity following acute or chronic use. Academic demands are the equivalent of "work" for an important segment of our population who are in school or vocational training programs. Acute and chronic drug effects on academic performance are expected to have an impact on the skills, work habits and subjective variables, such as motivation, mood and attitude, that, in turn, will influence future work performance.

One NIDA supported research project is specifically investigating motivational variables to validate the existence of an "amotivational state." Marihuana smoking appears to affect motivational aspects of daily living. Subjects who smoked marihuana worked hard to gain access to reward; however, when rewards became available, subjects did not engage in pursuit of the reward.

An evaluation conducted in collaboration with the National Highway Traffic Safety Administration (U.S. Department of Transportation), consisted of a laboratory assessment of the Los Angeles Police Department (LAPD) "Drug Recognition Program." In a clinical research laboratory volunteers were administered various drugs at varying dosages, under double-blind conditions and were then examined and evaluated for signs of drug intoxication by four trained LAPD officers using a modified version of the LAPD "Drug Recognition Battery." Results demonstrated that the procedures studied show a high degree of accuracy in correctly identifying intoxicated individuals and the class of drugs administered.

Dose Response Relationships and Pharmacokinetics

Pharmacodynamics is an area where quantitation is being applied to the time course of physiologic, psychologic and performance effects of drugs.

Integration of pharmacokinetics with pharmacodynamics is of significant importance to understand basic mechanisms governing drug actions and to establish the correlation of pharmacological response or performance with quantifiable drug concentrations in biological fluids. It is an area where innovative efforts are under research and development.

At present, the ability to predict the behavioral consequences of taking a drug is limited. Although generalizations have been established (for example: (a) high doses generally have a greater effect than low doses, (b) well-learned tasks are less affected by drugs than novel tasks, and (c) motivation is an important factor), the specificity with which one can predict whether an individual is capable of performing a specific task under the influence of a drug remains minimal. There is a clear need to examine the dose-response relationships of drugs on the performance of the simple and complex tasks of daily life, especially in the elderly.

Research proposals to study the time-course relationships of how drugs alter behavior over time, and the phenomena of "hangover effects", chronic intoxication, tolerance and dependence are sought by NIDA to develop knowledge in this area. Previous research has indicated that, with the exception of alcohol, the relationship between blood or plasma concentrations of drug and psychomotor performance is not well understood. Most studies have focused on absolute concentrations of the parent compound. Recent research has suggested that performance impairment/enhancement may be a function of the rate-of-change of drug concentration in blood for some drugs, or that concentration of active metabolites (vs. parent drug) may be more directly correlated with behavioral change. Research proposals to examine the relationships of drugs and metabolite concentrations, performance, and time-since-drug-administration to further elucidate these mechanisms are encouraged.

Development of Performance Assessment Batteries

The technology for detecting the presence of alcohol in biological samples from alcohol users is refined and the procedures well-established. At present it is even possible to accurately estimate blood levels of alcohol from the content of passively expired air. Currently, no such tests are available for most other drugs of abuse, including marihuana, opiates, central nervous stimulants (e.g., cocaine), minor tranquilizers or barbiturates. Intrusive means of obtaining biological samples (such as drawing blood) are generally problematic, and research to date indicates that behavioral impairment does not correlate well with the plasma concentrations of most drugs. Therefore, NIDA is interested in research aimed at exploring alternative non-intrusive ways of assessing drug-impaired functioning. Based on the burgeoning literature in behavioral pharmacology and complex human performance, it seems plausible that these current technologies could be applied to develop a single or perhaps small battery of test procedures to assess acute and chronic drug effects on psychomotor and cognitive performance.

Through a recent research grant announcement, NIDA encourages the development of compact portable devices to measure drug-induced behavioral impairment. These units must detect performance and/or physiological changes paralleling components of behavior associated with work (e.g., driving and use of machinery or high technology equipment and/or academic performance). Consequently, stimulus discrimination, timing, attention and memory, as well as response output, should be considered in the range of behaviors to be measured. Possible physiological measures include motor activity, event-related potentials, heart rate and visual functioning parameters. The units should be compact, portable, and suitable for use in diverse environments (e.g., at the roadside), and must be capable of being validated. The performance assessment battery should yield indices that are strongly and consistently correlated with changes in the criterion performance (e.g., driving). It should further provide indices that allow differentiation between the relative contribution to performance change by nondrug related factors such as fatigue, age, primary sensory or motor impairment, and drugs. Moreover, if drugs are judged as significant contributors to the impairment, the battery should provide at least an estimate of the classes of substance(s) likely to be involved (e.g., stimulants, depressants, hallucinogens, narcotics, and possible drug combinations).

INTRAMURAL RESEARCH PROGRAMS

Stress and Addiction

A variety of social and physiological factors may predispose an individual to initiate the abuse of drugs. Stress is one such key factor which plays a major role in both the initiation and maintenance of drug abuse. Stress produces profound and sustained biochemical changes in the body and interacts in a complex manner with psychotropic and addictive drugs. For example, opioids mimic the neurochemical and endocrine effects seen in response to stress, but attenuate the same hormone and neurotransmitter responses when administered in conjunction with stress. In addition, stress is known to produce neurochemical changes which may increase the efficacy of psychoactive drugs, thereby increasing the reinforcing properties of many drugs of abuse. Because of the role stress plays in drug abuse, studies of the mechanisms regulating stress responses, and the interactions between stress and drugs are essential to the understanding of the physiology and pharmacology of addiction.

Corticotropin-releasing factor (CRF) is the critical hormone involved with stress responses. The recent isolation, characterization and sequencing of a 41-amino acid peptide that fulfills the criteria of a physiological CRF opens new avenues for studying the mechanisms regulating stress. In addition to its role in regulating stress responses through the endocrine system, recent evidence suggests that CRF may act as a neurotransmitter to integrate the overall response of the body to stress. Most peptide hormones and neurotransmitters exert their action by interacting with specific receptors. Recently the ARC has identified receptors for CRF in the pituitary and in the brain. Current and future directions involve investigating various aspects of CRF and its receptors and the interactions among CRF, opioids, cocaine and other psychoactive drugs of abuse. Biochemical, cellular, pharmacological and neuroanatomical maps for CRF receptors, and studies on the modulation of CRF neurotransmission by various drugs of abuse may help explain the mechanisms underlying the interactions between stress and addiction. Furthermore, these studies will be useful in screening drugs that attenuate the deleterious effects of stress and block the reinforcing properties of drugs, thus addressing the stress-drug abuse relationship from both of these important perspectives.

Cocaine

Studies on drug-seeking maintained by cocaine injection have found striking parallels between behavior maintained in humans and that maintained in laboratory animals. These studies are designed to examine how drug-seeking behavior in humans and laboratory animals is related to subjective effects of drugs of abuse.

Cocaine is being studied using two fundamentally different laboratory approaches. In the first, subjects must work to obtain injections of various doses of cocaine or placebo. This approach enables us to study the role of the drug, itself, as well as the role of conditioning factors, in the development, maintenance, and the subsequent extinction, of persistent and compulsive behavior generally associated with cocaine dependence. In the second approach, cocaine injections are given by the experimenters according to rigorously controlled conditions, which enables the development of tolerance to the subjective and physiologic effects of cocaine to be assessed.

ARC laboratory studies of the self-administration of cocaine have confirmed anecdotol observations that cocaine's conditioning properties are remarkably powerful for human cocaine users, and have implications for both the understanding and treatment of cocaine dependence. Specifically, we have found that environmental stimuli paired with cocaine injections can sustain considerable amounts of behavior even in the absence of a forthcoming cocaine injection. Additionally, the powerful conditioning effects of cocaine are not necessarily associated with subjectively reported effects of the stimuli, suggesting that the conditioning process can be rather insidious.

Another series of studies have demonstrated that fencamfamine, a non-controlled compound illicitly sold as "fake cocaine", maintains cocaine-like drug-taking behavior under several experimental paradigms.

Future studies with cocaine will involve the assessment of compounds currently used, or proposed for use, in the treatment of cocaine dependence.

Opioid Agonists and Antagonists

Recent and current studies on multiple opioid agonists and antagonists have included the assessment of morphine, ketocyclazocine and cyclazocine. Administration of these compounds is sometimes preceded by the opioid antagonist, naloxone. Subjective, behavioral, and physiologic measures are used to quantitate and differentiate the effects of these compounds, and to facilitate the understanding of the biologic mechanism which underlie the effect of these compounds.

Our studies with multiple opioid agonists and antagonists have enabled us to differentiate the mechanisms of analgesia and drug induced euphoria. These findings will take us a step closer towards developing effective analgesics that will not produce dependence.

Studies with multiple opioid agonists and antagonists will incorporate recently developed opioids and opioid-like compounds to further assess the role of distinct drug receptor populations in the mediation of the responses to these drugs.

Nicotine

Nicotine studies conducted at the ARC involve the administration of nicotine in the form of tobacco, which is either inhaled or chewed, intravenous injections, and nicotine chewing gum. Nicotine administration sometimes follows pretreatment with other forms of nicotine, the nicotinic blocker mecamylamine, or other psychoactive drugs. These studies utilize behavioral, physiologic, electrophysiologic, neuroendocrine, performance, and psychometric techniques to assess the biologic basis and treatment of tobacco dependence.

Studies with nicotine have confirmed that nicotine is a prototypic dependence-producing drug, that nicotine produces many of the critical effects associated with tobacco use, and that there are objective, behavioral, and physiologic, rebound effects and deficits which occur during tobacco abstinence. We have also discovered that some of these deficits can be specifically blocked by treatment with an alternate form of nicotine. Studies of caffeine have begun to examine mechanisms of its psychomotor-stimulant effects, and have shown that caffeine can potentiate the reinforcing effects of nicotine.

Finally, in a preliminary examination of subject screening data, from the Addiction Research Center and the Addiction Research Foundation (Toronto), we found that there were positive correlations among the use of caffeine, alcohol, and tobacco within drug abusing populations.

VIII. UNDERSTANDING THE CHEMICAL COMPOSITION AND STRUCTURE OF DRUGS

One of the most basic tasks of drug abuse research is to understand the chemical composition and structure of abused drugs and endogenous substances. NIDA's research program in this area consists of three major components.

Synthesis of substances is basic to drug abuse research. New approaches have evolved which led to new research ligands for opiate receptor studies, new therapeutic compounds, and to economical means of preparing naturally derived analgesics. Synthesis is the critical process which must be successfully achieved if new drug designs are to be executed. The complex structural features often found in molecules of interest to drug abuse researchers necessitates continuing development of new and better ways of molecular preparation.

Interest in the development of new synthetic approaches to the opiate analgesics in current medical use is motivated by the desire to reduce dependence on foreign opium sources, and to improve the pharmaceutical materials available for the treatment of drug dependence.

Structure-activity relationships (SAR)

SAR is an area of basic molecular research which involves the chemical synthesis of homologous series of molecules with close structural relationships to commonly abused chemical compounds which have reasonably well characterized pharmacodynamic profiles. By correlating alterations in these profiles with the structural alteration of members of the homologous series, the structural specificity of the sites of action are elucidated in either qualitative or quantitative terms. These studies are directed toward a better understanding of the structural features and physiochemical properties of a wide variety of abused substances, their antagonists, and replacement drugs with lower abuse potential. Such studies provide basic direction for the synthesis of new treatment drugs and for the production of new chemical research tools.

Analytical

The development of methods for the analysis of drugs in biological fluids is important to pharmacokinetic, pharmacodynamic, and epidemiologic studies, and to prevention and treatment programs which are supported by detection technology.

Areas of need for analytical chemical development include more economical and reliable drug detection methods, more sensitive and specific methods for quantitation of drugs at very low concentrations, and new methods for detecting synthetic analogs, or so-called "designer drugs" which typically challenge the analytical chemist because of their low concentrations in body fluids.

EXTRAMURAL RESEARCH PROGRAMS

Program for Peptide Research

A major component of the NIDA's Research Technology Branch Program has been the synthesis, distribution (to researchers), medicinal chemistry, and analysis of opiates. Much of this basic research work has in fact laid the groundwork and provided the chemical tools for the discoveries of narcotic antagonists, opiate specific receptors, endorphins, enkephalins and related peptides.

The discovery of endogenous ligands for opioid receptors including enkephalins, endorphins and dynorphins, opened up the important research area of "opioid peptides." Later, evidence for the heterogeneity of opioid receptors was presented from a variety of in vitro and in vivo preparations. Furthermore, it has been proposed that opioid receptor subtypes differ in their conformational requirements and evidence for this has been presented from bioassays and binding assays. More recent discoveries have resulted in the isolation and identification of several other opioid peptides. "Opioid peptides" is now a very active research area in which scientists of several disciplines are involved. This area of research is still at an early stage of exploration and is an area of direct interest to the long range research goals of the National Institute on Drug Abuse. It is planned that new and expanded research programs pertinent to NIDA's mission in this area will be encouraged. Recently, NIDA issued a grant announcement to encourage and stimulate research particularly in the area of medicinal chemistry and molecular pharmacology of the opioid peptides and closely related neuropeptides.

Opioid peptides of general interest are enkephalins, endorphins, dynorphins, morphiceptin, dermorphins, and kyotorphins. Neuropeptides involved in inducing pain or analgesia are also of general interest. Although large numbers of peptide analogs have been synthesized, an analgetic that lacks the side effects of morphine has not yet been found. Other issues of interest concern the conformations of receptor-bound peptides, chemical characterization of receptor subtypes, precursor processing and related enzymology and development of analytical methodology for quantitative analysis in body fluids.

Present Research in Opioid Peptides

With NIDA support, the conformation-receptor selectivity of opioid peptides is currently under study. A number of conformationally restricted peptides will be synthesized and their conformations and receptor selectivities determined in solution and correlation will be attempted between conformation and the receptor selectivity.

NIDA plans to expand our present drug supply and analytical development resources in the peptide area and to stimulate research in several key areas by means of program announcements, technical reviews and publications. Examples of recent NIDA supported work in this area includes:

- The discovery this year by Dr. C.H. Li at the University of California at San Franscisco (UCSF) that naturally occuring Beta-endorphin fragments inhibit the analgesic action of Beta-endorphin itself has lead to the hypothesis that such "feedback" control of an active peptide by one of its own fragments may be a general phenomena in the regulation of biologically active peptides. Such a self-regulating system opens new speculation on the role of such systems in pain regulation and on factors that might adversely affect such regulation.

- Another NIDA grantee is working to synthesize opioid K antagonists, based on Diallyl dynorphin structure. If a K antagonists is synthesized, this will be a very valuable discovery, since there is not a single stable known peptide K antagonist available.

Structure-Activity Relationships

Quantitative Structure Activity Relationships

Traditional SAR drug design involving wide-range screening is costly and relatively time-consuming. In the past two decades, the combination of advances in theoretical chemistry and computing technology has created a major avenue of research for drug design in a much more sophisticated manner. The statistical and mechanistical correlations of pharmacological activity and molecular characteristics, commonly referred to as quantitative structure-activity relationship (QuaSAR) studies have become highly regarded as a basis for rational drug design. These methods are at the forefront of new technology in the basic science of drug design, drug receptor characterization in the brain, and studies directed at a better understanding of neuropharmacological activity of psychoactive compounds.

Several methods have been developed for QuaSAR studies, all of which involve the correlation of physiochemical properties (e.g. lipid solubility, molecular weight, atomic nature etc.) of drugs and their biological effects. A linear or non-linear relationship is established, which is then used as a data base to search for new molecules with desired biological property. Other studies use such correlations as the basis of describing the nature of the brain's drug receptor sites.

NIDA supported QuaSAR studies on narcotic analgesics and narcotic antagonists have found that subtle modifications of molecular conformation can effectively result in significant changes in biological responses of structurally similar compounds. QuaSAR, coupled with modern computing technology, serves as a powerful tool for better comprehension of the pharmacological effects, at the molecular level, of narcotic and narcotic antagonists and endogenous peptides that function as agonists and antagonists. Future efforts in QuaSAR research have great potential in the prediction and design of narcotic drugs useful for prevention and treatment of drug abuse.

Other QuaSAR studies have concentrated on anxiolytic agents and hallucinogens in attempts to understand the molecular bases of the complex behavioral pharmacology elicited by these compounds.

For example, one study conducted by Dr. Loew at the Standford Research Institute, is a multidisciplinary study of opiate receptor\interactions. Investigations span the synthesis of molecules, receptor binding, pharmacologic assay and quantum chemical calculation. Recent work includes the synthesis of a series of analogs of 4-m-hydroxy-phenylpiperidines which were then tested for pharmacologic activity for agonist and antagonist properties by the writhing and tail flick test. For the 4-hydroxy, 4-methyl, 4-n-propyl, and 4-t-butyl analogs with N-phenethyl, N-methyl, N-allyl substituent variation, compared to meperidine, morphine and N-allylnormorphine, the effects of the 4-R and N-R agonist and antagonist and antagonist activity were evaluated. Tentative conclusions are that N-R modulation of agonist/antagonist potency is not morphine like, the 4-R effects are more marked than those for N-R substituents, agonist potency varies inversely with chain length bound to 4-R. Molecular orbital calculations were also carried out on these compounds to study energy conformation parameters. The results are consistent with the in vivo experimental findings. The relative energies of a given structure over various conformations required for morphine-like conformers do not correlate with either experimentally determined receptor affinities or opiate agonist activity. An axial conformer always has lowest energy and, while it is not morphine-like, it could lead to agonist activity. The low energy equatorial conformation of the series of analogs could be responsible for the observed opiate antagonist effects.

Future work will in part focus on further developing the above findings by both added experimental and theoretical data gathering and analysis. In addition, work will continue on characterization of cyclic opioid peptides while new work is planned on B-endorphin properties.

Research conducted by Dr. Arthur Camerman of the University of Washington involves a crystallographic investigation of the three-dimensional stereochemical features of selected enkephalins and related opiate agonists and antagonists. The goal is to ascertain molecular features for compounds with specificity for mu and delta receptors.

Current efforts are focused on leucine enkephalin and methionine-enkephalin secondary structural analysis of intermolecular hydrogen-bonding related to structural flexibility and formation of pleated sheet conformations. In the next year efforts are planned to crystallize and analyze structures of metkephamid, morphiceptin, and related analogs.

Dr. David Nichols and his colleagues at Purdue University have completed the synthesis of a number of optically-active hallucinogenic phenethylamine and ergoline type compounds, including MDMA. They use the two lever-drug discrimination assay to assess *in vivo* activity for these compounds in rats trained to discriminate between injections of saline and LSD. In addition, expertise has been developed to use brain slices, in parallel with tritiated serotonin, dopamine and norepinephrine for the studies of the *in vitro* actions of the hallucinogens. These extensive data will help to characterize structure-activity relationship for different components of the biological activity and further our understanding of the mechanism of hallucinogenic action.

Over the past year he has expanded his effort to include studies on LSD in addition to the ongoing work with the hallucinogenic phenethylamines. Using NMR spectroscopy in studies of model receptors which interact with the phenethylamines Dr. Nichols is attempting to elucidate receptor characteristics of hallucinogens activity. Work on chemical synthesis of a series of alpha-methyl-tryptamine congeners has been underway and the expectation of completing a pharmacodynamic characterization of them during the coming year appears realistic.

Molecular Mechanisms

A variety of chemical and biochemical studies are directed at better understanding at the molecular level of mechanisms of metabolism and pharmacological action.

With NIDA support, Dr. Neal Castagnoli has begun to investigate the biomedical significance of iminium intermediates in common enzyme-mediated metabolism of tertiary amines. Iminium species are synthesized and tested with model compounds to assess intermediate complex formation. Ion trapping with radiolabeled anions is being used to determine specificity for iminium ion formation. This work will provide new insights into general metabolic mechanisms and in particular how such mechanisms influence drug toxicity through the formation of active metabolites. One specific compound of focused interest in this project is MPTP, the neurotoxic side product of a "illicit" synthetic heroin preparation. This work on MPTP is at the forefront of research on this fascinating and deadly compound.

Documentation of such formation with drugs such as phencyclidine (PCP), methylphenyltetrahydropyridine (MPTP) and morphine and the reaction of such intermediates with biomacromolecules is expected to provide insight into the molecular mechanisms associated with these amines as well as many other therapeutic agents with the tertiary amine structure.

A new theory for a general mechanism of neurotoxicity of amines by metabolic activation is being explored. Model compounds include MPTP (as above) and p-chloroamphetamine (PCA). Previous data from this project is supportive of the hypothesis that alkylating metabolites may covalently bind to tissue macromolecules. This covalent binding is species specific which is in agreement with the species specific neurotoxicity observed in animals. Oxidative metabolic activation of a compound to reactive and toxic metabolite may be a mechanism for the neurotoxicity observed for MPTP and PCA.

Structure-activity-relationshi studies of the molecular pharmacology of cannabinoid mechanism(s) of action has also been an active area of basic research due to NIDA support. Burstein has carried out extensive SAR studies on inhibition of testosterone, progesterone, rat brain cholesterol esterase, and stimulation of prostaglandins. Recently, Dr. Burstein forwarded the hypothesis of cannabinoid action occuring via a complex molecule formed from a biogenic amine with a cannabinoid short-lived metabolite. Attempts at isolating such an entity are underway.

Theoretical studies using quantum chemical calculations of electronic structures of the cannabinoids are being initiated by Dr. Reggio at the University of Georgia. This work will focus on SAR based ion molecular orbitals.

Receptors

With new developments in biotechnology and quantitative structural analysis, the potential for gaining highly specific insight into the nature (or actual presence) of brain receptors for psychoactive drugs has greatly increased. Two projects of note in these areas are involved respectively with hallucinogenic and cannabinoid receptors in the CNS.

The NIDA research project shared by Drs. Jack Peter Green and Harel Weintein is a multifaceted proposal which concerns the quantum mechanics and receptors of hallucinogens. These investigators have successfully combined theoretical chemistry and pharmacology to produce deep insights into the manners by which ligands and receptors interact in terms of binding and the activation of pharmacologic response. Five specific aims have been completed, including: 1) studies on 5-HT receptor linked to adenylate cyclase in adult brain homogenates; 2) chemical modification of sites associated with 5-HT receptors and binding sites; 3) studies on the kinetics of binding of LSD-like ligands to high affinity sites; 4) theoretical studies on the molecular mechanism of receptor recognition and activation; and 5) chemical synthesis of tryptamine and LSD derivatives. These newly developed methods of macromolecular structural analysis, in combination with quantum chemistry and molecular mechanics, will yield an understanding of the pharmacology of hallucinogens at a basic molecular level.

An innovative project to systematically search for biomolecules which act as specific receptors mediating the effects of THC, the primary active component of marihuana is ongoing at the Research Triangle Institute. The procedure involves a sophisticated generation of macromolecules via monoclonal antibody techniques.

These antibodies will be attached to a plastic surface which will in turn be used to separate from immunoglobulin fractions, the idiotypic antibodies resulting from animal immunization with THC antibodies. Experiments have already demonstrated the presence of such idiotypic antibodies from rabbit immunization.

These three experimental areas--THC antibody purification, idiotypic antibody formation by THC antibody immunization, and purification of the idiotypic antibodies by means of the plastic plates--is expected to yield the pure macromolecules which can be labeled, and bound to the (hypothesized) receptor sites for ultimate purification and characterization of such sites. This project will contribute greatly to our understanding of the basic biochemistry of the pharmacological activity of marihuana major psychoactive component.

Complementing this study is one underway by Dr. Solomon Snyder at Johns Hopkins University which involves the use of a new type of radiolabeled THC derivative in classical binding experiments with *in vitro* and subcellular module systems. The particular ligand used was produced by a one year collaborative effort between chemists on NIDA's main Drug Supply contract and Dr. Snyder.

This study, published in 1985, reported on competitive binding studies with a trimethylammonium derivative of THC (^{3}H-TMA), and over 40 different cannabinoids. It was found that ^{3}H-TMA itself binds saturably and reversibly to brain membranes to apparently one class of site. For some cannabinoids, potency in behavioral and physiological tests parallels their affinity for the ^{3}H-TMA binding site although several nonpsychotropic cannabinoids are active at this site.

Progress in this general research area should yield considerable improvement in understanding mechanisms of action for the cannabinoids and the hallucinogens. Over the next several years the understanding of hallucinogen mechanisms could reach the level now existent for the opioids, provided funding is increased to levels of research funding now provided in the opiate area. A localized computer for QSAR studies would be cost effective, as has been demonstrated by Industrial Laboratories, for progress in this area. Otherwise, individual grantees will be requesting increasing funds to set up local work stations.

Chemical Synthesis Research Program

Under this program, NIDA supports research in two primary areas: the development of analgesics and drug antagonists, and the development of new compounds for research purposes. In the analgesic/antagonist area, the program is about equally divided between the development of synthetic approaches to the production of morphine, codeine, and their related antagonists, and the synthesis of new compounds which hold promise as new analgesics or new narcotic antagonists. Current interest in the development of new synthetic approaches to the opiate analgesics is partially motivated by the desire to reduce dependence on foreign opium sources.

Usually this work on new research ligands overlaps with that concerned with the development of new analgesics and antagonists, so a grant directed at development a new synthetic approach to morphine, for instance, will produce compounds of research interest as opiate receptor ligands.

In 1980, NIDA initiated studies on the synthesis of the unnatural stereoisomers of naloxone and morphine for basic studies on the detection of stereospecific-(opiate receptor)-mediated pharmacological effects.

It is expected that the general availability of these opiate isomers will lead to new and valuable discoveries about the brain's opiate receptors and their function in neuronal regulation.

Research in the development of new research compounds includes work on the preparation of novel ligands for the characterization of opiate receptors, the preparation of previously unprepared metabolites of THC, and the preparation of novel peptide compounds based on the endorphin structure.

Total Synthesis of Opiates and "Unnatural Isomers" of Opiates

Recent collaborative studies between NIDA and the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDKD) on the total synthesis of opiates have now reached a stage where a clear alternative to reliance on foreign opium supplies may exist and where a source of extremely interesting and important new opiate compounds are now available.

NIDA initiated synthetic studies through its drug synthesis contract at the Research Triangle Institute (RTI) in collaboration with NIADDKD where certain key synthetic steps in opiate synthesis had been recently developed. NIDA's interest in this synthetic route resulted from the great demand by NIDA-supported investigators for the unnatural stereoisomers of naloxone and morphine for basic studies on the detection of stereospecific, therefore opiate receptor-mediated pharmacological effects.

These syntheses were successfully achieved and many investigators in the United States and several other countries have been supplied samples of the important new research compounds (+)morphine and (+)naloxone . The collaborative study has resulted in great refinement of the general synthetic procedures which could also be applied to the production of medically important opiates. There is every indication that the synthesis could be successfully executed on a large scale.

Another important aspect of this work is the great potential for discovery and development of new pharmacological agents in the unnatural(+) series of opiates. It may well be that highly potent non-narcotic antitussive drugs vastly superior to those in use today will emerge from ongoing pharmacological studies with the unnatural opiate enantiomers. This too could significantly affect the need for natural opium as a primary source of these drugs.

Efforts continued in 1985 on refinement of this synthesis and on the preparation of other opiates in this series. The unnatural isomer of codeine was prepared.

At the end of 1985, a NIDA Fellowship was awarded which will support synthetic studies at IAKKD to work out the synthesis of (+)etorphine, another unnatural isomer of great interest to opiate receptor research investigators.

Other grantees are actively involved in pursuing syntheses of morphine and related opiates using different synthetic approaches. Drs. White, Weller , Rapoport and Archer are actively involved in opiate synthetic research which promises improvements on the approach developed on the NIADDKD/NIDA collaboration as well as new antagonists for pharmacological testing and new ligands for the study of opiate receptors. These projects represent a very substantial base of present and future knowledge which will serve as a resource of material for furthering our understanding of pain, addiction and the means of treatment of these two phenomena.

IX. UNDERSTANDING THE METABOLISM AND DISTRIBUTION OF DRUGS

Pharmacokinetics, the quantitative study of absorption, tissue distribution and binding, biotransformation and excretion of a drug in the body, is well recognized for its importance in understanding the mechanisms of drug action and toxicity. Such information is also necessary in the design of effective strategies for drug detoxification. Pharmacokinetic studies establish details of the fate of drugs following different routes of administration such as intravenous, oral ingestion or smoking. It has also established that the effects of drugs can be related to plasma concentrations of the drug, or its active metabolite(s), rather than to the dose administered.

For example, pharmacokinetic studies of nicotine have led to the hypothesis that smokers regulate their nicotine intake to maintain a desired nicotine effect. It was also found that daily nicotine intake was correlated with the number of cigarettes smoked and with nicotine clearance. Studies of the effect and disposition of cocaine found that approximately half the dose was thermally degraded when smoked. The blood cocaine profile following smoking was very similar to that resulting from intravenous injection, and maximum cocaine blood levels were reached in 5 minutes. In one study, the subjects also perceived that the "high" effect very quickly reached a maximum effect 5 minutes after intravenous and 7 minutes after smoking administration. Following nasal administration, it was found that the absorption of cocaine was slow and prolonged as the maximum cocaine plasma levels was reached in 30-60 minutes. The "high" effects also rose slowly and lasted longer than from smoking and intravenous administration. These data are important to the clinical explanations of the patterns of cocaine abuse and may bear on the development of effective cocaine treatment strategies.

EXTRAMURAL RESEARCH PROGRAMS

Information on metabolism and disposition of a drug is essential for the understanding of how a drug affects the body. It further provides basic information necessary for the design of effective strategies for the treatment of drug intoxication as well as for the treatment of drugs of abuse. Research in this area involves the identification of metabolites, the elucidation of metabolic pathways, and the characterization of pharmacokinetics, which is a quantitative description of distribution and binding, and metabolism and clearance, of a drug in the body. Through the years of NIDA funded studies, a body of information are available on metabolism and pharmacokinetics of cannabinoids, phencyclidine, cocaine, opioids, etc. It has also been established that the effects of drugs can be related to plasma concentrations of the drug or its active metabolite(s) rather than to the dose administered. Several grants are currently funded for the identification of active metabolites and their disposition relative to the pharmacological effects of the drug and to the characterization of pharmacokinetics as well as its correlation with pharmacodynamics of the drug.

An important new publication based largely on grant and contract research programs at NIDA will be published in 1986 entitled "Pharmacokinetics and Pharmacodynamics of Psychoactive Drugs." This is a critical up-to-date collection of findings and developments in the basic biomedical research areas of pharmacokinetics and pharmacodynamics.

Phencyclidine (PCP)

There has been considerable speculation that PCP is sequestered in tissues. With NIDA support, Dr. Billy Martin is investigating the tissue sequestration of PCP and, more importantly, PCP metabolites in acutely and chronically treated animals. Since PCP is very commonly abused by smoking, studies will also initiated to identify PCP pyrolysis products and to quantify their delivery in smoke. Phencyclohexene was shown to present in the smoke condensate that is in agreement with results published before. The effectiveness of urine acidification due to multiple treatment with ammonium chloride for the alteration of the biodisposition of PCP were shown in rats.

Dr. Mayersohn, who initiated studies of PCP disposition and pharmacokinetics in an animal model has moved into a new area, immunotoxicokinetics. He explores the use of PCP-specific antibodies as a means to promote PCP elimination and therefore to reverse PCP toxicity. Preliminary studies in dogs indicate that this is a fertile and promising area for investigation.

Several interesting unanticipated developments arose in their efforts to clone anti-PCP antibodies. Initially two lines were developed with differing affinities. That with the desired high affinity turned out to be unstable in antibody production. In attempting to use the same cell lines for further antibody production they encountered problems with sufficient relative PCP-protein conjugate stability but no PCP binding. This latter antigenic phenomenon apparently develops during the haptenation process and it has been observed before.

This investigation could lead to the development of effective treatment approaches for PCP toxicity in humans as well as for other drugs. It is expected that the information and concepts developed by Dr. Mayersohn will form the basis of a broad research area in drug abuse treatment using the rapidly developing biotechnology of monoclonal antibody production in designing effective clinical treatment modalities of drug overdose toxicities.

Investigations by Dr. Cho at the University of California, have isolated a new metabolite of PCP which is being tested for pharmacological activity. Its structural analogy to gamma-alpha-butyric acid (GABA) is the basis for speculation of neurotransmitter "correlate" functions. Current efforts for 1986 involve an in-depth examination of the metabolism of the heterocyclic ring system of PCP since this is the dominant pathway in man. Detailed and basic studies on the metabolism of this ring system are important because the ring system in common to other drugs including cocaine and fentanyl. Basic mechanistic and metabolic data generated from this project will thus be useful in understanding and predicting these phenomena for other drugs.

Cannabinoids

It has been suggested that cannabinoids are sequestered in the deep tissue compartment and slowly eliminated in humans. Recent evidence showed a very prolonged elimination of THC metabolites in urine after discontinuation of marihuana use. Pilot Studies by Dr. Hollister, at the Veterans Administration Hospital at Palo Alto, California, indicate that plasma levels of THC can be followed for more than 8 days after marihuana abstinence in heavy chronic marihuana users. Studies will be continued to define elimination kinetics of THC in heavy chronic users and also to investigate the effects of THC on performance.

THC is known to be eliminated from the body mainly by metabolism. Although numerous metabolites have been identified in humans, a great portion of metabolites have not yet been identified. Another new NIDA sponsored grant, has been awarded to identify the metabolites and also to elucidate their exercetion kinetics in the urine. As urinalysis is now widely used for screening of drug use, this information will be useful for the confirmation and validation of urinalysis.

Research of the late Dr. Leighty's suggest that THC persists in rat tissues as fatty acid conjugates of the cannabinoids and that the marihuana flashback may be resulted from the conversion of the fatty acid conjugates to the respective unconjugated active metabolites. Continuation of her work by Dr. Fentiman indicates that the fatty acid conjugates of THC and codeine both have similar effects as their respective unconjugated drug on behavioral and neurochemical parameters in rats. Future work will continue to investigate the importance of the fatty acid conjugates of drugs of abuse as related to its adverse effects.

Cocaine

Research on cocaine by Dr. Reese Jones, at the University of California at San Francisco, has focused on benzoylecgonine, a major metabolite of cocaine. The pharmacokinetics of the metabolite were determined and found to have little measurable pharmacologic effect. However, preliminary data shows an interaction with the pharmacokinetics of the parent drug as it seems to inhibit cocaine elimination. Since cocaine is eliminated primarily via metabolism, this observation supports the earlier observation of a Michaelis-Menton product inhibited metabolism. The reported volume of distribution for benzoylecgonine suggests some tissue binding and the half-life is much longer than that for the parent drug.

Future work is aimed to complete the studies on pharmacologic properties of cocaine and on complete protein binding studies.

In another NIDA investigation, metabolic studies conducted by Dr. Jindal, at the Nathan S. Kline Institute of Psychiatric Research, use sophisticated gas chromatography-mass spectrometric methods to identify the metabolic pathways of cocaine in rats. Benzoylecgonine, ecgonine methyl ester, ecgonidine, norcocaine, N-hydroxynorcocaine, hydroxycocaine and hydroxy- methoxycocaine were found to be the major metabolites, while benzoyl- norecgonine, and cocaine-N-oxide seem to be present in trace amounts. Dimethoxyhydroxycocaine is tentatively identified. Several of these newly identified metabolites of cocaine are present in fairly large concentrations, are expected to cross the blood-brain barrier and could contribute towards long range toxicological effects of cocaine. Research continues to investigate the distribution of cocaine metabolites in other biofluids and tissues and further to understand the mechanisms for cocaine toxicity.

Cocaine Research Initiatives

Considerable research is ongoing on many aspects of cocaine abuse. One area where limited knowledge exists is that of coca paste, a primary form of abused cocaine in Latin America. While coca paste has not been extensively imported to the US, basic information would be important to have in case such illegal importation does occur and also for purposes of assisting Latin American governments with their own abuse problems.

Studies are therefore planned on studying the chemistry of coca paste which includes its potency, toxic adulterants or side products from the illicit laboratory processing of paste, and the particular problems which might be associated with the smoking of this particular dosage form of cocaine. Preliminary evidence from Colombia seems to indicate a particularly acute problem of heavy use of this form of the drug which leads to mental and physical pathology which may be due more to the properties of the paste and its route of administration rather than to the drug itself. The studies will initially be centered at our contract with the University of Mississippi because of their experience with this material.

Studies are planned in cooperation with the Peru government to study the chemical make-up of these paste samples obtained to assess its toxicity in animal inhalation studies.

Nicotine and Tobacco Cigarettes

The role of nicotine and its metabolites on the effects of tobacco smoking and the development of tobacco tolerance is under investigation by Dr. N. Benowitz. Nicotine is eliminated from the body by metabolism. The rate of nicotine metabolism is also an important determinant for individual differences in smoking behavior. Data indicate that habitual smokers metabolize nicotine more rapidly than nonsmokers. A rapid metabolizer requires more nicotine intake to maintain a given body level of nicotine. Therefore, the development of a tobacco habit may involve metabolic tolerance. It was also found that men metabolize nicotine faster than women. Thus, men may need to smoke more than women to achieve the same body level of nicotine.

Studies to determine the importance of nicotine on the effects of cigarette smoking showed that the amount of nicotine consumed had little effect on the magnitude of cardiovascular response and that changing nicotine intake per se might not alter the risk of sudden adverse cardiac events associated with smoking.

Further research will continue to investigate the effects of nicotine abstinence, nicotine exposure, the effects of carbon monoxide or other combustion products of tobacco on nicotine metabolism, the mechanism for the development of tolerance, and the contribution of other tobacco alkaloids to cigarettes consumption and adverse effects.

Opioids

The studies of clinical evaluation of l-acetyl methadol for possible use in treatment of narcotic addiction and in the management of pain are carried out by Dr. Inturrisi. Biochemical and pharmacological methodology in evaluating acute and chronic effects of alkaloid opioids in animals and man has been improved.

Clinical correlates on effects of electroconvulsive shock on circulating B-endorphin were confirmed, and biodistributional and pharmacological responses to infusions of naloxone were defined. Additional advances have included the mastery of required biochemical techniques that are necessary for continuation of this work.

Future Directions of Metabolic and Pharmacologic Studies

Research efforts on metabolism and pharmacokinetics should continue to elucidate the ultimate fate of drugs in the body and to establish the relations between effect and blood (or biological fluid) concentration. Multidisciplinary approaches should be carried out to correlate the pharmacokinetics with pharmacodynamic measurement. In view of the increasing frequency on the street of "designer drugs" and the predominate use of coca paste in Latin america, pharmacokinetic studies for these substances should also be supported to understand the mechanisms of adverse effects of these drugs.

Limited information is available on the mechanisms of drug actions after chronic use and when taken with other drugs. Future research should also be directed to investigate the pharmacokinetics of drugs after chronic use or when taken in combination with alcohol or other drugs. this research will provide a better insight into mechanisms of drug tolerance, dependence and drug interactions in general.

Factors such as age, sex and genetics may also affect a drug action. Investigations should also be conducted to determine whether these effects are pharmacokinetics or metabolism in nature.

With increasing attention on the animal welfare, research efforts should also be directed to the design of in vitro models for the predicting of drug metabolism and pharmacokinetics in vivo as well as for the predicting of effects in vivo.

X. PROVIDING TECHNOLOGICAL SERVICES IN SUPPORT OF DRUG ABUSE RESEARCH AND PREVENTION

While major breakthroughs in our understanding of the basic biological and behavioral processes in the health field are often widely publicized, the major and minor technological breakthroughs that made these discoveries possible are usually ignored. This has always resulted in problems in finding support for efforts to improve research methodologies. However, in the last two decades it has become an exceptionally serious problem because of the pace and breadth of technological advances that have been made.

For example, fifteen years ago most drug abuse research was conducted with purified samples of abused drugs. Obtaining these drugs was difficult only because of their illicit nature. Now, however, because of major technological advances such as PET and NMR scanning, the use of monoclonal antibodies, immunoassays, and high performance liquid chromatography, a whole new set of substances have become crucial to progress in the drug abuse field. These include radio-labled drugs, endogenous substances, receptor agonists and anatagonists, and structurally altered versions of abused drugs. Many of these substances have few, if any, commercial uses and are either not commercially available or available only at great expense. NIDA currently produces these substances through a contract and provides them to grantees free of cost. Unfortunately, however, because the importance of this program to our overall research effort is not realized, support for the production of these substances has not kept pace with increases in support for the research that relies on them.

EXTRAMURAL RESEARCH PROGRAMS

Research Resources

NIDA's Research Technology Branch provides a variety of materials and services for research support. The resources are made available to qualified researchers whose work falls within the programmatic interests of the Institute.

The resources include the Drug Supply Program which provides investigators conducting basic research in the drug abuse area with authentic and standardized chemicals, drugs, metabolites and dosage forms. These include stimulants, hallucinogens, narcotic antagonists, cannabinoids and marihuana. Many labeled compounds are also available which incorporate deuterium, tritium, ^{14}C or ^{125}I isotopes. Dosage forms available for research involving humans and experimental animals include marihuana cigarettes; THC capsules; naltrexone oral solution, tablets and implant pellets; acetylmethadol (LAAM) oral solution and morphine implant pellets.

New compounds are frequently added to NIDA's inventory based on demand from the research community. A NIDA resource update is planned which will list newly added chemicals or services which will be mailed periodically to all grantees.

The Analytical Services Program provides radioimmunoassay (RIA) kits for the analysis of delta-9-THC and 9-carboxy-THC (the primary metabolite of THC).

Analytical resources are also available for investigators working in the endorphin area. Endorphin standards sets contain various endorphins and potential cross-reacting materials, specific antisera against [Met^5]-enkephalin and beta-endorphin and a complete RIA kit for beta-endorphin are available.

Other components of the analytical program concentrate on quantitative methods directed at the development of improved methods for measuring drug levels in body fluids and tissues and providing these services to drug abuse researchers. A wide variety of projects are supported by this program including studies on pharmacokinetics, behavioral pharmacology, drugs and human performance, classical drug toxicology, etc.

Production of Cannabis and Related Analytical Services

The source of all cannabis material used for research in the U.S. comes from our contract with the University of Mississippi. This contract is to provide for both production of cannabis materials and the analysis of such materials. Cannabis is used in a large variety of research projects supported by NIDA. Between one and five acres of cannabis are generally grown each year, followed by careful quantitative analysis and storage prior to shipment to researchers in this country and abroad.

In addition to analysis of the grown material, analyses are also performed on approximately 100 samples of confiscated marihuana each month which are provided by the Drug Enforcement Administration. These analyses provide a means of determining potency trends of illicit marihuana by determination of tetrahydrocannabinol (THC) concentrations and also of screening for herbicide contamination which might create a public health problem.

Such production was established in the late 1960's by the government and the present contract is a continuation of that effort.

The production and distribution requires frequent analyses of both growing and stored material to determine optimum harvesting time in the first case and potency stability in the second.

Approximately eight years ago, NIDA was asked by Congress to initiate a collaborative relationship with the DEA to monitor the potency of illicit marihuana. This highly successful program carried out under the Mississippi contract has provided NIDA, DEA and interested Federal agencies with a comprehensive base of information on the potency of marihuana with respect to time (1973-present), geographical area of confiscation, type of marihuana (loose leaf, brick, Thai stick, sinsemilla, etc), and many other factors useful to DEA and NIDA in assessing illicit distribution patterns and potential for health impact.

During 1987 this potency monitoring program will continue to assess the strength of domestic and foreign sources of cannabis.

Analytical Chemistry Development

Analytical methods are essential to basic studies of any drug. Major efforts were directed at this research area by NIDA starting in 1972. Through research contracts and grants, methods were established for the measurement of low nanogram concentrations of THC and its metabolites in body fluids by the techniques of radioisotope measurement, radioimmunoassay (RIA), gas chromatography/mass spectrometry (GC/MS) and liquid chromatography. In the case of marihuana, this effort was particularly challenging because of the unique problems associated with cannabinoid analysis due to its low concentration in body fluids, the difficulty of separation from interfering substances in blood and urine.

A major emphasis in the last few years has been on making these techniques available to the research community both through the distribution of pure compounds for investigators to further developments in the area and also by providing services via contracts to perform analysis of body fluid samples from preclinical and clinical studies being conducted by numerous investigators throughout the world. These services are provided without charge to the investigators through the mechanism of several NIDA funded service contracts. (see previous section of Research Resources)

Several grants are presently associated with the development of new and potentially far-reaching quantitative analytical techniques. At the McMaster University in Tronoto, Dr. Rosenfeld, is entering its third year of effort on the development of a unique extraction and derivatization method for cannabinoids in biological fluids. This addresses one of the greatest roadblocks to a facile assay for marihuana components in biological fluids. This project is being carried out in close collaboration with one of the analytical service contracts mentioned above. Findings of the research grant can thus be quickly incorporated into the contract to provide the most efficient and up-to-date service to the researchers who make use of the contract. Progress has been excellent and a working system is expected to be published within a year.

Another grant project involves a new and highly innovative approach to solve one of the major problems limiting the effective use of homogeneous fluorescent immunoassays, that is, the extraction of a very weak signal embedded in high background noise. This technique, phase-resolved fluoroimmunoassay promises simplicity and minimal reagent requirements as advantages to presently available techniques for drug assay by homogeneous immunoassay. Progress continues to be very good in the 2nd year of this effort.

During the past two years the new SBIR program has generated a number of funded projects associated with the development of new innovative analytical techniques for detection of marihuana use by body fluid analysis. Several projects are in their first phase of development and two have moved into phase II. These projects include development of highly specific monoclonal drug antibodies and their incorporation into rapid and specific assays for marihuana components in urine and blood. Another project involves the development of critical fluid chromatography for the analysis of cannabinoid metabolites.

One project has produced several monoclonal antibodies to THC and is moving rapidly toward a new immunoassay based on the ELISA system which should be more economical and perhaps more sensitive than currently available immunoassays.

Herbicides - Pyrolysis

At the request of Drug Enforcement Administration (DEA), NIDA in collaboration with NIH, has conducted a pyrolysis study of herbicides (glyphosate and 2,4-D) via a NIDA contract (271-80-3802). The herbicides are candidates for use in the eradication of marihuana in the United States and other countries. These studies indicated that glyphosate was almost completely decomposed and 2,4-D was partially decomposed when smoked on marihuana. This data will be used as part of the basis to assess the potential health hazards of smoking marihuana contaminated with such materials. It has been cited in several Environmental Impact Statements prepared by the DEA.

Synthetic Analogs

Tremendous interest has developed during the past year on the "designer" drug problem. These are synthetic substances which are similar to known controlled substances but which are structurally slightly different. This slight synthetic alteration means they are not technically illegal to possess or synthesize and can therefore be produced as substitutes for heroin, amphetamine, and hallucinogens which are legally controlled. Since it takes a few weeks at least for any single substance to be placed under emergency control by the Drug Enforcement Administration (DEA), a clever chemist can continually alter his synthesis and remain relatively immune from prosecution while maintaining his supply.

There has been a rapid and in depth response from NIDA in responding to the potential threat these types of compounds present. Over a dozen of these have been synthesized through NIDA's Research Drug Supply Program for abuse liability testing and to serve as analytical standards for DEA laboratories. They have also been provided to NIDA grantees who are investigating their pharmacology and neurotoxicity.

During the next 3 years, many more synthetic variations of the fentanyls, meparidines and methamphetamines are expected to appear on the street. This proliferation could become a major new source of public health problems. During the next several years, increasing emphasis will be placed on studying the basic pharmacology, metabolism and detection of these types of compounds. Concurrent with these basic research efforts will be the even more important effort to evolve new means of rapid "street detection" of the existence of new components and the suppression of their synthesis and distribution.

Further, interagency agreements have been established with DEA and CDC to further the production and distribution of these compounds to forensic laboratories and State health organizations. These efforts will allow more rapid identification of new drugs on the market and control and prosecution of underground synthetic analog chemists.

In May 1985, 400g MDMA was prepared at the request of DEA for abuse liability studies. In June 3g 3-methylfentanyl was also prepared at DEA's request for use in their labs as a standard and for abuse liability testing.

In September and October, 1985, 10 additional fentanyl analogs were prepared for research use and abuse liability testing.

A large number of other synthetic analog drugs are planned for synthesis throughout Fiscal Year 1986. Hopefully this rapid response to a potentially massive public health problem will serve to suppress the evolution of these new dangerous, and sometimes lethal, drugs of abuse.

OVERVIEW OF DIRECT OPERATIONS

The Direct Operations account supports salaries and administrative expenses of NIDA personnel and provides support for a limited number of programatic activities. Generally, programs directly operated by NIDA encompass the management of research programs, dissemination of research findings, transfer of knowledge leading to the development of better prevention and treatment programs or approaches, and application of abuse liability data in the process of domestic and international scheduling of drugs.

The direct operations account is NIDA's sole source of support for efforts to stimulate and assist State, local and private sector involvement in drug abuse prevention services. For example, direct operations funds are used to support the development and dissemination of prevention campaigns such as the "Just Say No" Campaign. The "Just Say No" Campaign is directed at teenagers and their parents and involves the support of 500 community groups in the sponsorship of "Just Say No" Clubs. The formation of the first "Just Say No" Club was a spin-off of the Oakland Parents in Action organization, a minority community effort supported in part by NIDA. It is now the fastest growing prevention program in the country. In FY 1987 efforts will be made to increase the participation of minority communities in the campaign and to incorporate the program into elementary and junior high school programs.

A cocaine media campaign is also being developed, directed at 18 to 34 year olds, and will enlist the support of leaders of industry in the development and distribution of radio, television and printed messages directed at employees, supervisors, employers, and families. Efforts will be made to reach high school and college students and to involve the music and sports industries, both of which can have a profound affect on the attitudes of young people, in the delivery of prevention messages.

One of NIDA's highest priorities is to mobilize various State, local, and private organizations who have demonstrated an interest in becoming more involved in drug abuse prevention. Current efforts include the National Prevention Network, a joint effort with the National Institute on Alcoholism and Alcohol Abuse (NIAAA) and State prevention coordinators to provide a mechanism for sharing knolwedge and resources in the prevention field; the Ethnic Family Initiative, which stimulates and assists the formation of local family groups in minority communities across the nation concerned with drug abuse prevention programs; a joint effort with Links, Inc., a natinal black women's service organization, to assist them in the development and operation of drug and alcohol abuse prevention programs for black youth; a program with the Optimists International to help them develp and sponsor "Just Say No Clubs."

NIDA has also initiated an effort to provide more information on the dangers of synthetic analogs of controlled substances. NIDA is producing pamphlets, brochures, and other materials appropriate to various age groups at risk for these drugs and is providing technical assistance to State and local officials on the availability and dangers of these drugs. NIDA is also developing press releases, news bulletins, and conferences to inform the public of the dangers of these substances.

NIDA supports these efforts through the provision of technical assistance and a variety of other services. One of the most important of these is the development of prevention materials including pamphlets, books, and audiovisual materials. For example, during 1985, NIDA published 43 new publications, including 27 for the scientific community and 16 for the general public. An additional 39 publications were reprinted. We expect these numbers to increase during 1986. Prevention materials available from NIDA, include small pamphlets like the "Just Say No" flyer designed for distribution to adolescents and their parents, technical manuals on how to organize, operate and evaluate community prevention programs such as the "Prevention Evaluation Workbook," and a variety of films that can be used in prevention programs. NIDA encourages the distribution of these materials through the National Clearinghouse for Drug Abuse Information. Last year the Clearinghouse answered over 83,000 requests for information on drug abuse and distributed over 3 million publications in response to inquiries related to the "Just Say No" Campaign. NIDA is also providing training in the use of prevention evaluation statgegies to encourage prevention programs to assess, and where appropriate, improve on their prevention efforts.

Restricting the supply of drugs with known abuse potential has been a common feature of governmental efforts throughout the world to maintain the health and safety of their citizens. A critical factor in the process of determining if a substance should be controlled, is an assessment of the relative abuse liability it may pose to the individual and society. Using its intramural and extramural research programs, NIDA plays a major role in efforts by the United States Goverment to place appropriate controls over drugs due to their potential for misuse or abuse.

There are currently two International Conventions of which the United States, and most other Western nations observe. The Single Convention on Narcotic Drugs was enacted in 1961 to stem the illicit traffic of narcotic drugs. Under this international treaty member countries agree to yearly quotas on the production of opium and to exert control over the import and export of opiate-based substances. later, a second treaty was drafted to help countries control the international distrubution of non-narcotic substances. This treaty, "The Convention on Psychotropic Substances," was ratified by the United States Senate in 1980. The United States Government meets its administrative responsibilities under these international agreements through the joint efforts of the Departments of State, Justice, and Health and Human Services. Under both Conventions, drug scheduling decisions are based on consideration of several factors, such as the drug's legitimate medical use (if any), its abuse potential or appearance in illicit drug distribution networks, and the resulting economic impact of a particular scheduling decision. In scheduling actions of either Convention, the Department of Health and Human Services (HHS) is responsible for developing the medical and scientific information needed to place substances in various schedules and thereby control their distribution. Principal among the health and scientific decisions made by HHS are determinations of the adequacy of scientific research on the substance, including the appropriatness of treatment restrictions imposed by prescription and refill limitations.

In the United States, the Department of Justice has been designated by Congress as the lead agency for international drug scheduling activities concerning narcotic substances pursuant to the Single Convention. With the enactment of the "Psychotropic Substances Act of 1978," (Public Law 95-633), Congress designated the Department of Health and Human Services as the lead Federal agency for international drug scheduling activities pursuant to the Psychotropic Convention. Within HHS, the National Institute on Drug Abuse shares this lead responsibility with the Food and Drug Administration.

At NIDA, the review of dependence producing drugs is part of the Institute's role, since 1978, as a WHO Collaborating Center. Through its Office of Medical and International Affairs, NIDA staff prepare comprehensive literature reviews of medical and scientific studies bearing on particular substances. Information about the abuse liability and illicit trafficking, provided by other member countries to the UN Secretary General, is combined with these literature reviews, resulting in a dossier on each substance for which an international scheduling recommendation will be offered. Eventually, these dossiers are reviewed by governmental experts of member countries, as well as interested private sector parties, such as pharmaceutical companies and consumer organizations. A formal hearing is convened jointly by the Food and Drug Administration and NIDA allowing non-governmental reviewers an opportunity to provide comments and views prior to HHS's determination of scheduling recommendations.

Through its role as a WHO Collaborating Center, NIDA also provides an opportunity for foreign visitors to learn about drug abuse demand reduction strategies in the United States. Over the past year over 100 international visitors, mostly health professionals, were recieved by NIDA officials.

Over the past several years, NIDA has collaborated with WHO on research projects involving a reassessment of the health and behavioral consequences of cannabis use; a review of diagnostic classification of substance abuse in mental health nomenclature; and, a review of research on drugs and driving, with an emphasis on the identification of drugs in body fluids to estimate impaired driver performance.

I. Prevention Activities

NIDA Drug Abuse Prevention Repository

The Repository has grown by over 300 documents in the past year, bringing the total collection to around 4,600. The computerized portion of the system has been valuable in providing bibliographic listings of materials coded to specific topics used by staff in answering requests received by mail and telephone. Materials housed in the Repository include books, journal articles, tapes, microfiche, reports, speeches and curricula. Besides the special efforts made to locate materials dealing with such areas as smoking intervention strategies, cocaine and drug abuse school curricula, materials relating to AIDS and intravenous drug use are now being collected for inclusion in the Repository.

Ethnic Family Initiative

The Oakland Parents in Action Project, a minority community mobilization program developed and implemented by a predominantly black parents' group in Oakland, California, will serve as the model in 1986 for implementing similar parent projects in four cities having significant ethnic minority populations.

During 1985, NIDA focused on organizing ethnic minority communities and began work on a process guide, patterned after the approaches and techniques employed by the Oakland Parents in Action Project. This guide will assist local communities to organize similar groups to prevent drug abuse among minority youth. Replication of the Oakland model is underway in four sites--Atlanta, Georgia, Corpus Christi, Texas and the Hopi Indian Reservation in Arizona. Parent involvement programs and "Just Say No" clubs are already an integral part of each site's program. In FY 1987, a fourth site will be chosen to replicate the Oakland model.

A new initiative with the Links, Inc., a national black women's service organization will involve on-site technical assistance in the form of a workshop for representatives from Links local chapters and specific black women's organizations. The purpose of this workshop is to build skills in starting drug and alcohol abuse prevention programs for black youth. Following this workshop, the Institute will provide technical assistance to the organizations as programs are implemented. Initially, pilot projects will be started in 12 cities in 4 regions of the country between November 1985-March 1986. These projects will represent an expansion of existing innovative Links' programs and will incorporate a variety of drug abuse prevention program ideas, such as special seminars for women, emphasizing the dangers of drug use for adults and youth and formation of "Just Say No" clubs. All projects will be documented and shared with other organizations with the expectation that they can and will be implemented in other areas of the country. The Links' projects represent the first attempt of any organization to implement a national grass-roots program in black communities.

The network capacity-building component of the Links program expects to produce a significant increase and expansion of prevention programs, especially among programs implemented by college-trained blacks.

Cocaine Prevention

A plan for dissemination of a cocaine resource package prepared by NIDA has been implemented. Announcing the availability of the material to the field has produced an unusually large number of requests for the package. At least 350 mailings have been made to individuals requesting them, and to major national and State organizations.

Two meetings on the topic of cocaine were held in 1985. The first meeting was held at the Institute last fall. Several private-sector service clubs were stimulated to develop cocaine prevention efforts; PRIDE, Boys Club of America, the National Federation of Parents and the organization of Lieutenant Governors. The purpose of the second meeting, held in March, 1985, was to stimulate discussion of activities and promote voluntary action for cocaine prevention efforts developed among the public- and private-sector organizations represented. "Cocaine: A Symposium," a meeting held in April, jointly sponsored by NIDA and the Wisconsin Institute on Drug Abuse in Madison, Wisconsin, was a unqualified success. Over 500 attended. It provided health professionals, concerned citizens and industry representatives an opportunity to share information about the cocaine problem and discuss prevention strategies with national experts. Another organization focusing it's activities on cocaine prevention is the the Alcohol and Drug Problems Association (ADPA). Institute staff presented a seminar on cocaine to several training coordinators of the Education Department's Drug and Alcohol Abuse Prevention Team Training program in Memphis in May, and prepared a cocaine resource package which contains a history of cocaine, current research findings and a list of treatment resources.

Activities for Fiscal Year 1987 will include moderating a seminar on cocaine prevention at the Alabama Governors' Conference on Drug Abuse in November. The conference will include Statewide representatives from various professions interested in drug abuse prevention. A special issue of *Prevention Networks* is being developed on cocaine for distribution during 1986. A plan is being developed for dissemination of this publication as well as the cocaine resource package.

Off-Site Technical Assistance

The "800" line has been an important resource in planning local prevention initiatives and programs. Because of the heavy volume of work, "standardized" letter formats have been developed and used, increasing the efficiency of the system. However, some personalization is still necessary for many responses.

Significant off-site technical assistance activities during Fiscal Year 1985 are described below.

"800" Telephone Technical Assistance Line

Calls received during FY 1985 requiring off-site technical assistance averaged between 75-100 per month; over 7,000 requests have been responded to since the "800" line was installed in April of 1983. Many letters are received and responded to as well. Two unanticipated surges of calls were received during FY 1985; the "800" number was broadcast on an Hour Magazine program, aired in December and in an issue of *Women's Day* magazine reaching the newsstands in late February. 250 calls were received regarding the former; 150 calls from the latter. Information packages for each were prepared with mass mailing in mind. For FY 1987, an analysis will be undertaken of the effectiveness of the system and changes in its operation made accordingly.

Optimists International

NIDA staff helped the Optimists International Clubs to develop and sponsor "Just Say No" clubs through a training workshop in St. Louis December, 1985.

National Federation of Parents Networkers Seminar

NIDA staff also worked with the National Federation of Parents for Drug-Free Youth (NFP) and ACTION in hosting a meeting with the NFP State Networkers. ADAMHA is supporting travel costs, coordinating a Federal panel and preparing a report on Federal agency efforts in prevention. Other activities include workshops on resources, fund-raising and volunteerism. The meeting was held in November, 1985 at the Mayflower Hotel in Washington, D.C.

Handicapped

A National Substance Abuse Prevention Conference for the Handicapped is planned for November of 1986. NIDA is providing resources and technical assistance for this conference, believed to be the first of its kind ever conducted.

Closed captioning of the public service announcements (PSAs) developed for the "Just Say No" campaign was accomplished by the National Captioning Institute and open captioning, for use over cable TV, was provided by Gallaudet College. Copies of the captioned PSAs are available for loan from NIDA. They made their debut as part of ADAMHA sponsored activities in October, 1985 for Handicapped Month. Plans for budgeting and structuring NIDA's future media campaigns will include costs for closed-captioning and distribution of the tapes to the networks and other closed-circuit and public channels.

Plans for Fiscal Year [illegible] include conducting a technical review about drug abuse and the [illegible], providing support for the National Alcohol and Drug Abuse Prevention Conference [illegible] in Iowa, and continuing to collect and network [illegible] assistance efforts.

On-Site Technical Assistance

NIDA fosters prevention program development at the local level by paying partial costs of expert consultation. Providing travel expenses for the consultants [illegible] has been instrumental in the growth of prevention activities [illegible]. Careful analysis of requests and effective negotiation [illegible] between NIDA and local programs. [illegible] knowledge has been disseminated through this mechanism [illegible] the "Just Say No" strategy. Another is provision of on-site technical assistance [illegible], a national organization of Black professionals [illegible] prevention programming in Black communities [illegible].

Key on-site technical assistance [illegible] included the following activities conducted by NIDA's Pyramid Project:

Saying No [illegible]

Several peer resistance skills development curricula exist. One of a number for which NIDA has provided support, is the Life Skills Training curriculum developed by Dr. Gilbert Botvin of the [illegible] Medical College. The Arkansas State Prevention Coordinator requested a NIDA representative to come to Little Rock, Arkansas [illegible] toward implementation of Dr. Botvin's Life Skills Training curriculum as well as a press conference [illegible]. As part of the Institute's efforts to [illegible] technical assistance was provided to [illegible] in Arkansas. If [illegible], this will be the first large-scale implementation of the program in a [illegible] setting.

"Just Say No" Clubs

The "Just Say No Club Movement" is the fastest growing drug abuse prevention program in the country. The formation of the first "Just Say No" club was a spin-off activity of the Oakland Parents In Action Organization, a minority community effort supported in part by NIDA. Planning meetings with the National Broadcasting Corporation (NBC) in New York, Optimists International in St. Louis, and both Optimists and NBC in New York have resulted in an agreement to sponsor this prevention movement. A meeting to coordinate efforts with a wider interest group was held in October, 1985. Participants included the National Federation of Parents, National School Boards Association, American Association of School Administrators, National Association of State Alcohol and Drug Abuse Directors, National Association of Elementary School Principals and National Prevention Coalition. Staff of the Pyramid Project are developing an issue of Prevention Networks for NIDA

Contraceptive Evaluation

Research in contraceptive evaluation will be supported in the following areas: steroid contraceptives and other exogenous sex hormones, including continued investigation into the association between reproductive system cancer and long-term exposure to currently marketed contraceptive steroids, studies of the physiologic and metabolic changes that are found to occur in oral contraceptive users, and evaluation of the benefits of contraceptive steroids such as putative protective effects against certain diseases; intrauterine devices (IUDs), including evaluation of the effects of IUDs in the occurrence of undesired infertility, studies of the mechanisms by which IUDs cause pelvic inflammatory disease, and investigations of how various infective agents enter the uterus of a woman with an IUD; sterilization, including studies on the long-term health effects of female sterilization, studies to ascertain the relative safety and quantify the failure rates of the established and newly emerging procedures used for female sterilization, and studies to quantify the recent findings that men who are vasectomized have a longer life expectancy; and barrier methods, including studies to ascertain and quantify the reduction in the risk of venereal disease and pelvic inflammatory disease among women who use barrier methods, evaluation of the use-effectiveness of barrier methods, including the new contraceptive sponge, and estimation of the role of barrier methods in the genesis of newly documented gynecological disorders, such as toxic shock syndrome.

Demographic and Behavioral Sciences

Research in the demographic and behavioral sciences will be supported in the following areas: adolescent pregnancy and childbearing, including determination of the long-term consequences to teenagers of bearing a child at a young age; trends in fertility, including the analysis of fertility trends in the U.S. by social and economic characteristics; fertility and family planning, including identification of the interacting factors which contribute to effective fertility regulation; family and household structure, including evaluation of the effects of family structure on child health and development; status and roles of women, including analysis of the interrelationships between women's status, roles as wife, mother and labor-force participant, and the number, spacing and timing of births; child care and fertility, including studies of how costs and availability of child care influence decisions regarding employment and childbearing; consequences of population change for families, including evaluation of the influence of health issues on fertility decisions, particularly with regard to delayed childbearing; cost and value of children, including analysis of the extent to which men and women with varying characteristics evaluate the costs and benefits for various numbers of children and the timing of births; migration and population distribution, including investigation of the relationship of immigration to health status, kin networks, and fertility; and factors affecting mortality, especially infant mortality and mortality associated with reproduction.

FOOD AND DRUG ADMINISTRATION
FAMILY PLANNING

Food and Drug Administration (FDA) programs, within the Department of Health and Human Services (HHS), are authorized by the Food, Drug and Cosmetic Act of 1938, as amended. FDA approves contraceptive drugs for safety and effectiveness before they are marketed and maintains surveillance over contraceptive drugs, contraceptive devices containing drugs and releasable metals, and "non-drug" contraceptive devices (those which do not incorporate releasable metals or drugs) after they are marketed. The Medical Device Amendments of 1976, enacted on May 28, 1976, provide FDA with the authority for more extensive regulatory controls over contraceptive devices such as intrauterine devices (IUDs) and intravaginal devices. FDA involvement in population research and family planning services is directed toward:

> Sponsoring or monitoring the progress of research necessary to carry out its regulatory responsibilities relating to oral contraceptive safety.
>
> Using its regulatory functions to assure the safety and effectiveness of contraceptive drugs and devices.
>
> Maintaining a reporting system which serves as a clearing-house for information concerning adverse reactions associated with contraceptives.

The first oral contraceptive agents were approved by FDA for general use in 1960. In 1976 the marketing of sequential oral contraceptives was discontinued. By 1978, over 60 oral contraceptives were on the market.

FDA published the "Second Report on the Oral Contraceptives" in August 1969 and its Obstetrics and Gynecology Advisory Committee continues to assist in activities related to family planning. This Committee, rechartered in 1977 as the Fertility and Maternal Health Drugs Advisory Committee (FMHDAC), has participated in revising oral contraceptive labeling, in updating guidelines for clinical investigations of oral contraceptives, and in evaluating the influence of estrogen content on the thromboembolic action of oral contraceptives.

The Committee has also deliberated upon the problem of the tumorigenic action of certain steroidal contraceptives and has assessed the safety and efficacy of certain systemically administered contraceptives and IUDs incorporating a releasable metal or a hormone.

In April 1983, the FMHDAC reviewed and discussed the animal testing programs for establishing long-term safety of contraceptive steroids at a workshop co-sponsored by FDA and National Institute of Child Health and Human Development (NICHD). In December 1983, the Committee considered the possible teratogenicity of vaginal spermicides and concluded that currently marketed vaginal spermicides pose no teratogenic risks.

FDA provides expert advice to the pharmaceutical industry and the academic community in the conduct of studies to obtain data on the safety and efficacy of contraceptive drugs. In addition, FDA solicits the views of consumers and other interested parties on proposed consumer information materials to accompany the contraceptive market package.

FDA initiated several research projects during the past 15 years to develop adequate information to assure the safety and effectiveness of contraceptive drugs and devices. The agency supported investigations of the potentially carcinogenic and other chronic effects of certain oral contraceptive steroids in long-range studies in Rhesus monkeys and beagle dogs at the International Research and Development Corporation in Mattawan, Michigan. These studies followed the protocol prescribed by FDA to the pharmaceutical manufacturers in 1967. The long-range investigation is intended to provide some indication of the possible carcinogenic hazard to long-term human users of the contraceptives, as well as any other possible toxicity to target organs or systems. The studies were completed, with the Armed Forces Institute of Pathology providing a repository for all records, tissues, blocks and slides pertaining to the studies. All adverse effects, particularly tumorigenicity, carcinogenicity, diabetogenic potential and endocrine imbalance have been studied during the course of the contract. On the basis of these studies, and those performed by industry on some products, several administrative decisions were made over the past 10 years: to stop clinical investigations on some products, to cease marketing of some marketed products, to limit the clinical investigation and use of one product, and to permit continued investigation and use of still other products. In addition, FDA has required long-term dog and monkey studies on all estrogen and progestogen chemical entities used for contraceptive purposes.

PL-480 funds have been used to support research on the effects of oral contraceptives (OCs) on patients. One small study in Zagreb, Yugoslavia confirmed the effects of the early OCs on decreasing glucose tolerance. Another large prospective study in Ljubljana, Yugoslavia showed an association between use of OCs and increased incidence of neoplasia of the cervix uteri (Andolsek et al (1983) *The Lancet* ii:1310). Another paper on this study was published in *Contraception* 28 (6) 505-519, 1983. This study tends to confirm the work of Vessey et al (1983) *The Lancet* ii:930-934. Although the overall incidence of carcinoma *in situ* and severe dysplasia in oral contraceptives users was not statistically significantly different from the non-users, there was an age specific increase in the incidence of carcinoma *in situ* in a restricted oral contraceptive use group. An increased number of invasive cervical carcinomas was found in the OC users (3 in the prior user group and 3 in the non-prior user group). The authors suggested that steroid contraceptives might act as a promoting rather than initiating effect on the development of cancer of the cervix. FDA is in the process of modifying OC labeling to reflect increased concern in regard to the possible associations of OC use and cervical carcinomas.

A collaborative study using PL-480 funds began in 1970 in Sarajevo, Yugoslavia under the direction of G. Zarkovic to study changes in Pap smears over time rather than studying for incidence of neoplasia *per se*. The study involved married women living in rural areas around

Sarajevo who had not used OCs before and who had a Pap smear Class I or II to start. About half the women were Moslem, and half were Christian. Of 11,240 women entered into the study 5,532 chose to use an OC, Stederil, later changed to Stederil-M with less estrogen. This is like Wyeth's Lo-Ovral. The others were non-users. Rates of progression from Pap II to III were not different between users and non-users. Rate of regression from III to II was higher among users than non-users (15% vs 6%) but numbers were small. Only 5 cases of confirmed cervical cancer were found in the entire group, 3 cases in non-users and 2 in users. Christians did not have more dysplasias than Moslems. The women were studied for about 7 years. The study population was too small to produce statistically significant results to evaluate the incidence of cervical neoplasia, which was rare in this cohort. A second study in Sarajevo involved a statistical analysis of all births and stillbirths (7,339) in 3 large hospitals in Bosnia to determine if the use of OCs, or of hormones during pregnancy, would be associated with congenital anomalies. No such association was found, but comparatively few women had used OCs.

There were data to suggest that use of hormones (presumably progestogens) to treat threatened abortion, was associated with low birth-weight babies. Cases were few, and threatened abortion may itself be linked with low birth-weight babies.

Three projects related to basic research in animal reproduction were conducted in 1983 by FDA's Division of Drug Biology. One publication (Alleva, JJ et al (1983) Endocrinol 112:2095-2106) on induction of estrogen and progesterone receptors and decidual reaction in the hamster uterus by cholera toxin) suggests a sequence of events involving receptors, natural hormones and synergism in uterine cell multiplication. This may be a simple, precise, and specific bioassay for cholera toxin, and it may not be found in other rodent species.

A study by Alleva, unpublished, dealt with the pineal gland and its hormone, melatonin, and the induction of a sterile period in female hamsters by melatonin. Pinealectomy results in cyclic activity, despite changed light/dark cycles as in winter (long periods of darkness). in winter this seasonal breeder is usually acyclic and sterile. Melatonin may have a function in diurnal cycles in other mammals.

Another study, by A.W. Jordan investigated the paradoxical reaction of human gonadotropin (HCG) in both stimulating and inhibiting steroidogenesis *in vitro* in rat ovarian luteal cells. Inhibition is due to a loss of HCG receptors and a decrease in adenylate cyclase activity, plus a decrease in the activity of protein kinase, an enzyme which mediates the effects of cyclic AMP. The suggestion is that initial peptide stimulation of luteal cell C-AMP formation results in a dissociation of the two subunits of protein kinase and during the period of dissociation the cell is refractory to further peptide stimulation. Cell responsiveness returns upons reassociation of the existing subunits and/or synthesis of additional subunits.

Another study by Tagaki and others is investigating the effect of prenatal exposure to anticonvulsants in rats. In view of ancedotal reports of reproductive anomalies in the daughters of women receiving barbiturates or phenytoin during pregnancy, behavioral and reproductive functions are being measured in the progeny of female rats receiving phenytoin and phenobarbital during pregnancy. Preliminary results indicate that at oral doses of 40 mg/kg some irregularity in estrus may occur but no significant results on reproductive performance were seen. The project is continuing.

Two drugs of current interest, Depo-Provera, as a contraceptive, and Norethindrone enanthate injectable contraceptive are still maintaining Investigational New Drug (IND) status. Norethindrone is still being researched by its sponsor with FDA reviewing the reports. A Public Board of Inquiry (PBI) concerning the status of Depo-Provera for contraception was held on January 10-14, 1983, and a subsequent meeting was held on pathologic findings of uterine tumors in Rhesus monkeys in August 1983 following a rereading of studies by experts in Rhesus pathology. On October 26, 1984, the PBI submitted its decision to Commissioner Young and placed its report on file in the FDA's Docket Management Branch. The report stated that Upjohn's supplemental new drug application for Depo-Provera as a contraceptive agent does not contain reports of investigation adequate to show that the drug is safe for use under the conditions prescribed, recommended or suggested in the labeling as required by section 505(d)(1)(2) and (4) of the Food, Drug, and Cosmetic Act, and the information contained in the supplemental new drug applications, combined with other information about the drug, does not provide a sufficient basis from which the FDA can determine that Depo-Provera is safe for general marketing in the United States. Upjohn has requested and was granted a 60-day extension of the deadline for filing an exception. Until Upjohn's exception is filed the Commissioner cannot make a final decision on the approvability of the application.

In the areas of disseminating information, the FDA Drug Bulletin published articles on: (1) caffeine and pregnancy and the approval of Riutodrine for premature labor in November 1980; (2) indications for Bendectin and the teratogenicity of nitrous oxide in March 1981 (subsequently, Bendectin was withdrawn voluntarily from the market by its manufacturers); (3) the Surgeon General's advisory on alcohol and pregnancy and adverse reactions from treating premature labor with Beta agonists in July 1981 and; (4) the use of pelvimetry x-ray examinations in November 1981. An article appeared in the July-August 1983 Consumer on the Today vaginal sponge.

In addition, as as part of the Consumer Education Program, FDA Consumer Affairs Officers speak at high schools and at various civic gatherings, distribute posters, and prepare video tapes about drugs including oral contraceptives and estrogens. The FDA issues timely Talk Papers about concerns of current interest.

There were two reports concerning oral contraceptives in Lancet, October 25, 1983. One of the articles, by M.P. Vessey, et al ii, 930 suggested that long-term use of the pill may increase the risk of cancer of the uterine cervix. The other article, by M.C. Pike, et al (Lancet ii 926, 1983) related to increased risk of breast cancer after prolonged use of higher strength progestin preparations, used before the age of 25 years. Dr. Pike's findings are contrary to those of CDC published in JAMA (March 25, 1983, pp 1591-1600). On November 10 and 11, 1983, FDA, NIH, and WHO officials as well as the investigators involved in the CDC study met with the authors of the two articles. The consensus at that meeting was that further analysis of Dr. Pike's findings are necessary. The CDC investigators felt that further analyses should be performed on their data. In February 1984, the Fertility and Maternal Health Drugs Advisory Committee considered the issues of the association of OCs with breast and cervical cancer. The Committee concluded that a significant increase in risk for the development of breast cancer had not been demonstrated in any subgroup of oral contraceptive users or with any particular OC. In regard to cervical carcinoma the Committee reaffirmed its previously suggested modification of OC labeling to reflect increased concerns.

The most recent issue involving oral contraceptives concerns the development of multiphasic regimens by the manufacturers. This involves altering the dosage of hormones throughout the cycle. These alterations in hormone dosages approximate the natural and physiologic hormone levels throughout the cycle, and thereby provide maximum safety and a reduction in intermenstrual bleeding, and still maintain a good efficacy rate.

The first biphasic regimen (Ortho 10/11) was approved in January 1982. In 1984, three triphasic OC regimens were approved 7-7-7 (Ortho), Trinorinyl (Syntex) and Triphasil (Wyeth).

The oral contraceptive physician and patient labeling has been revised. In an effort to produce factual, current and concise labeling brochures that are easily understood by both the physician and the patient, and yet contain all information essential for making decisions on use of the oral contraceptives, the FDA Fertility and Maternal Health Drugs Advisory Committee in August 1981 recommended that the labeling be revised. The proposed revised labeling is being reviewed for final approval.

The one-size-fits-all Today vaginal contraceptive sponge was approved by FDA in April 1983 for over-the-counter sales. The sponge consists of a polyurethane foam matrix impregnated with 1.0 gram of spermicide, nonoxynol-9. It fits into the upper vagina and provides protection against pregnancy for up to 24 hours after insertion. Shortly after its introduction, cases of Toxic Shock Syndrome were reported in patients who used the sponge. Labeling was changed to reflect the increased concern in regard to a possible association of the sponge and Toxic Shock Syndrome. As of November 1984, 12 cases of Toxic Shock Syndrome had been reported in association with sponge use. By October 31, 1984, 21.1 million sponges had been distributed (Faich et al JAMA 255: 216-218, 1986).

FDA's Biological Product Experience Division (DD&BPE), through a cooperative agreement with the Drug Epidemiology Unit (DEU) of Boston University, has supported the study of drug exposures, including contraceptives and fertility related agents, among approximatley 60,000 hospitalized patients, and 5,000 birth defect pregnancy outcomes. As a follow-up of observations in the Walnut Creek and Royal College of Physicians studies, DEU examined possible associations of oral contraceptives with malignant melanoma and regional enteritis. A DEU study by Helmrich SP et al on "Risk of Malignant Melanoma in Relation to Oral Contraceptive Use" (JNCI 72: 617-620, 1984) showed no association. The regional enteritis study found an association with regional enteritis. A DEU study by Rosenberg L et al (American Journal of Epidemol 119: 167-176, 1984) on "Breast Cancer and Oral Contraceptive Use" found no association.

Findings from these studies were presented in a November 1983 National Institutes of Health workshop. The DEU is focusing on additional breast cancer hospitalizations which could have had prolonged high dosage exposure beginning at an early age. The DEU published one of several studies finding a protective association for ovarian cancer with oral contraceptive use, and for endometrial cancer. DEU also continues to contribute to the retrospective analysis of oral contraceptives relative to other factors associated with myocardial infarction with the latest publication, Rosenberg et al, "Myocardial Infarction in Women Under 50 Years of Age" (JAMA 250: 2801, 1983). DEU also presented negative findings on the association of spermicides with birth defects at the December 1983 Fertility and Maternal Health Drugs Advisory Committee meeting (previously published Shapiro S et al: "Birth Defects and Vaginal Spermicides" JAMA 247: 2381-2384, 1982). The DEU is also continuing an enlarged retrospective study of this question in collaboration with the Columbia University spontaneous abortion registry.

In a second cooperative agreement with the Boston University Collaborative Drug Surveillance Program (BUCDSP), a drug and contraceptive experience is followed in a cohort of 280,000 members of the Group Health Cooperative of Puget Sound. BUCDSP also presented at the Fertility and Maternal Health Drugs Advisory Committee meeting in December 1983 its findings of an association of birth defects and spontaneous abortions with spermicide use.

Under a contract for the Computerized On-line Medical Pharmaceutical Surveillance System (COMPASS), patient profile information is obtained from Medicaid management information systems covering 1.6 million recipients in Michigan and Minnesota. Approximately a third of these women are in the reproductive age group. More than 100,000 oral contraceptive recipients have been identified, whose diagnostic profiles have been compared to those in an age matched sample of non-users. An analysis of "Relationship of Oral Contraceptives Estrogen Dose to Age", based on these data were published by S. Van de Carr et al in the Am J. Epidemol. 117: 153-159, 1983. This analysis illustrates not only the confounding influence of the association of high dosage with older age in epidemiological associations, but also a public health problem requiring patient education. Another interesting preliminary observation from this data base is the influence of bromocriptine given for suppressing lactation on early ovulation with resultant short birth interval, possible beyond that expected from curtailment of lactation amenorrhea.

Under another DD&BPE contract, FDA obtains national estimates of drug use from IMS America. An analysis of "Oral Contraceptive Use Trends" since 1964 has been prepared and presented.

FDA's Epidemiology Development Branch also comparatively analyzes birth defect data from both exposure cohort and defect registry studies, including DEU, BUCDSP and COMPASS mentioned above, as well as drug experience case reports, and other sources. From this analysis the possible association of spermicides, oral contraceptives and other fertility related drugs with birth defects has been monitored. A recent report by McCredie et al of a 23.9 fold relative risk for a limb defect in offspring of mothers exposed to oral contraceptives after conception (The Lancet, ii 623, 1983) has not been confirmed in other available data, including a case control screen of 83 limb reduction defects at the DEU. The possible association of progestogens with birth defects has been comprehensively analyzed and examined in data from the Hungarian birth defect registry member of the International Clearing-house of Birth Defect Monitoring, in which more than 20% of mothers have been exposed. No associations have been confirmed. The possible association of spermicides, has also been comprehensively followed. Relative to a previously alerted association of trisomy chromosomal birth defects with ovulation induction agents, a 21st case was found in the large birth defect registry in Lyon, France. An alert and publication based on 10 cases of female fetal virilization with oanazol (a testosterone derivative anterior pituitary suppressant) was also provided.

In December 1980, FDA published the report and proposed Monograph of its Advisory Review Panel on Vaginal Contraceptive Drug Products for Over-the Counter Use. This advance notice of proposed rulemaking recommended that FDA require diagrammed instructions over and above the written labeling information so that proper usage of OTC vaginal contraceptive drug products is enhanced. FDA is currently reviewing the Panel's recommendations and public comments, and is developing a tentative final regulation.

In the June 5, 1971 FEDERAL REGISTER (revised and clarified on March 7, 1973), FDA published a proposal to make intrauterine devices (IUDs) which incorporate heavy metals, drugs, or other added substances, "new" drugs. Thus, a "Notice of Claimed Investigational Exemption for a New Drug" must be submitted to the FDA to cover clinical investigations of the safety and efficacy of contraceptive devices containing copper or progestrone. Moreover, an approved New Drug Application is required for marketing such devices since they remain under the jurisdiction of FDA's Center for Drugs and Biologics. Under the "new drug" procedure, four New Drug Applications (NDAs) have been approved for the marketing of medicated IUDs.

On February 25, 1974, an NDA for Cu-7 (Intrauterine Copper Contraceptive Device) sponsored by G.D. Searle and Company was approved; on February 4, 1976, an application for Progestasert (Intrauterine Progesterone Contraceptive System) sponsored by Alza Pharmaceuticals Division of Alza Corporation was approved; and on November 4, 1976, an application for Copper T Model T Cu 200 B (Intrauterine Copper Contraceptive Device) sponsored by the Population Council was approved. This latter drug is now manufactured and distributed by G.D. Searle and Company under the trade name Tatum-T.

These approvals were made with the condition that additional studies be performed to collect specific information after marketing. At the present time, the Cu-7 physician's labeling recommends replacement every three years. The labeling for Copper-T states that it must be removed and a new one inserted on or before 36 months from the date of insertion. For the Progestasert, which releases a hormone gradually over a one-year period, the device must be replaced after one year.

FDA authority, prior to passage of the 1976 Medical Device Amendments, was to prevent misbranding or adulteration of non-drug intrauterine devices. FDA maintained surveillance over such marketed devices to ensure their safety and efficacy within its authority. As a result of the Medical Device Amendments of 1976, those IUDs which are not classified as drugs were placed under the control of FDA's National Center for Devices and Radiological Health.

In June 1974, when the safety of the Dalkon Shield IUD was brought into question, the FDA set up an ad hoc Obstetrics an Gynecology Advisory Committee to evaluate the available data and make recommendations to the Commissioner on the safety and efficacy of the IUDs in general and the Dalkon Shield in particular.

In addition to evaluating the safety and efficacy of the Dalkon Shield, the Committee endorsed the concept of professional and patient labeling of IUDs to ensure that physicians and patients are kept fully informed on the safety and efficacy of both drug and non-drug IUDs. A final physician and patient labeling regulation was published in the FEDERAL REGISTER on May 10, 1977 and became effective November 7, 1977.

On May 28, 1976, the Medical Device Amendments of 1976 were signed into law, giving FDA the authority to approve devices for safety and effectiveness before they are marketed, and to maintain surveillance over such devices after they are marketed.

FDA convened advisory panels to assist in classifying medical devices into three regulatory classes: Class I, General Controls; Class II, Standards; and Class III, Premarket Approval. Final regulations were published in the February 28, 1980 FEDERAL REGISTER classifying the following devices into the Premarket Approval category: IUDs, tubal occlusion devices, and hysteroscopic devices for female sterilization. Classified into the Standards category were: abortion devices, laparoscopic and culdoscopic devices for female sterilization, and diaphragms.

FDA has classified fertility prediction devices with the concurring recommendation of the OB/GYN section of the OB/GYN/Radiology Devices Advisory Panel into Class I (General Controls). These devices use basal body temperature and cervical mucous as a means to determine ovulation.

FDA now approves new types of non-drug IUDs, new types of tubal occlusion devices and hysteroscopic devices for female sterilization for safety and effectiveness before they are marketed, and maintains surveillance over such devices after they are marketed. FDA also requires the submission of safety and efficacy data on those non-drug IUDs and tubal occlusion devices that are already on the market and which have never undergone premarket review. Under the provisions of Section 515(b) of the Act, devices on the market prior to passage of the Medical Device Amendments may remain on the market for at least 30 months following their classification into Class III. After the 30 months grace period FDA may initiate a procedure to call for the submission of data to support claims of safety and efficacy for these devices on a class by class basis. The Agency published a proposal to call for such submissions for non-drug IUDs in 1985. The two pre-amendments device IUD's have been withdrawn from the market; the Safe-T-Coil in 1982 and the Lippes Loop in 1985, so the Agency does not anticipate receiving applications.

FDA will use the most cost-effective regulatory alternatives to address performance of Class II contraceptive devices. These include but are not limited to development of standards, guidelines, publication of educational and technical information, and voluntary initiatives by manufacturers to solve device problems.

If FDA determines that a device presents an unreasonable risk of substantial harm to the public health, it has the authority to ban the device, to require manufacturers to notify all health professionals, and to seize the product or enjoin the manufacturer. In addition, manufacturers are required to keep records on device experience and to report deaths or serious injuries to FDA. The FDA will continue its research relating to contraceptive devices to ensure their safety and efficacy.

While there is an abundance of scientific literature and research on drug and non-drug IUDs, it was largely uncoordinated and of limited value to those who insert IUDs. Therefore, FDA contracted with the Battelle Pacific Northwest Laboratories, Human Affairs Research Center, to assist in updating the 1968 "Report on Intrauterine Contraceptive Devices." The contract was submitted to FDA on August 11, 1975 and was utilized in developing FDA program responsibilities.

Based on the comprehensive review and analysis of the scientific and clinical data, the report attempts to identify:

Clinical studies in which there is valid evidence of the effectiveness of both drug and non-drug IUDs.

Any hazards associated with drug and non-drug IUDs.
Any physiological and histochemical effects produced by IUDs other than contraceptive effects.

The mode of action by which the contraceptive effects are produced.

Criteria and procedures for use in the selection and insertion of IUDs.

The nature of the information which should be made available to physicians and patients.

In 1985, under the Investigational Device Exemption (IDE) regulation 2 additional protocols were approved to study the safety and effectiveness of cervical caps for contraceptive purposes, bringing the total number of cervical cap studies in progress to 89. Because FDA considers pregnancy to be a significant risk to health, an approved IDE is necessary to sponsor a cervical cap study. The IDE regulation became effective in July 1980, and allowed sponsors with approved protocols the freedom to collect data on the safety and efficacy of the cervical cap without having to comply with certain other provisions of the Act. These studies are currently ongoing and are closely monitored by the bioresearch monitoring program and review of the sponsor's required annual report.

A pamphlet entitled "Contraception: Comparing the Options" was updated in 1980. This publication gives a concise evaluation of contraceptive options ranging from effectiveness of various family planning options to the long term effects of contraceptive methods on the ability to have children.

During 1981, FDA directed a voluntary standards conformance assessment activity on condoms. Four manufacturer's products were tested for conformance to ANSI/ASTM D3577-78. Results indicate that 96% + 3% of condoms manufactured appear to be in substantial conformance with the critical parameters of the voluntary standard.

In 1982, as a result of a petition requesting reclassification, FDA reclassified the condom with spermicidal lubricant from Class III to Class II. This will permit it to be commercially available without undergoing premarket approval.

FDA continues to assess the risks to fetal development from exposure to ionizing and non-ionizing radiation. It also promotes consumer and professional education programs to encourage prudent use of diagnostic radiation examinations of pregnant women. Specific activities include:

A pamphlet, "X-rays, Pregnancy and You," was published which discusses the special considerations necessary to protect the developing fetus from adverse effects of radiation. This pamphlet is available in both English and Spanish.

A poster was prepared and distributed for display in physicians offices, clinics, and radiology departments to remind pregnant women to inform the doctor of their pregnancy before obtaining an x-ray.

In response to growing interest and concerns, FDA examined video display terminals to determine if a radiation hazard to pregnant women existed. No hazard was identified. FDA will continue to monitor these devices through a program of testing and surveillance.

In cooperation with professional organizations, FDA has continued an aggressive effort to determine the effects of ultrasound on the developing fetus.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Bureau of Health Care Delivery and Assistance

FAMILY PLANNING

The Division of Maternal and Child Health of the Bureau of Health Care Delivery and Assistance is involved in the provision of family planning services through the support of individual States which have chosen to provide such services as part of the Maternal and Child Health (MCH) Services Block Grant. Prior to enactment of the Omnibus Budget Reconciliation Act (P.L. 97-35), family planning services were among those supported through the MCH formula grants program to States. Since enactment of the Block Grant legislation, States have responded to service needs in the family planning area in ways which reflect the particular circumstances of each State. Many States have combined Title X and Maternal and Child Health activities into a coordinated health care focus. Among the States, the degree of financial support for family planning services coming from the MCH Services Block Grant varies from no direct support to a significant proportion. Information on this topic is not required in the Block Grant annual reports, and therefore precise data on this subject are lacking. Federal Maternal and Child Health staff provide consultation and technical assistance concerning family planning programs as part of their general responsibilities to assist States in development of comprehensive maternal and child health care service systems.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH RESOURCES AND SERVICES ADMINISTRATION

INDIAN HEALTH SERVICE

Family Planning

The Indian Health Service (IHS) provides comprehensive Family Planning services to all American Indian and Alaska Native men and women who request such services. The goal of these activities is to assure that every child that is conceived will be a wanted one and be given the opportunity to reach his/her full potential. A very important part of the effort is that information and services will be presented in a culturally sensitive and effective way.

Specific activities have been developed and implemented that reached the adolescent and pre-teen population groups. In addition to effective educational activities, programs geared at enhancing the self-image and esteem of individuals in these age groups have been integrated into our comprehensive health care delivery system. In this way, it is assured that the number of unplanned pregnancies will decrease.

Efforts continue to increase the availability of services to couples who desire children and yet are unable to realize that goal. Infertility services and adoption services in coordination with other agencies are provided within limited available resources.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Bureau of Health Professions

FAMILY CARE

Family nurse practitioner programs prepare registered nurses to provide comprehensive primary care. They function in a role that involves clients in both the assessment of their health status and decisions affecting their health care. Care is provided to all family members across all ages. Particular emphasis is given to teaching individuals and families about health promotion, disease prevention and health maintenance activities. Approximately $4,500,000 was awarded in the area of family care in FY 1985.

In FY 1985 the Nursing Special Project program awarded $201,892 for activities in family care. These project included support for improvement of clinical nursing practice through the incorporation of health promotion and health maintenance concepts during all stages of the life cycle within the family constellation.

The Nursing Research Grant program awarded $688,507 in FY 1985 to residencies and support for projects studying the effect of family nursing on sibling response to dying, family response to the mother's antenatal hospitalization, the effect of antepartum stress on family functioning, family recovery from the situational crisis of open-heart surgery, similarity between parents and twin off-spring in terms of Type A behavior, and the impact on families of the mother's having breast cancer.

The Family Medicine training program is aimed at reversing the significant downward trend in the number of general practitioners which has occurred in the past. These programs support the development of family medicine faculty and family medicine graduate and predoctoral training programs so that additional family practitioners will be available to enter the health care delivery system. Funds referenced are the total amount appropriated for the Family Medicine and Residencies Training Program. This program also addresses other national priority initiatives, such as long term care and aging.

Centers for Disease Control
Center for Health Promotion and Education
Population and Family Planning

In the United States, more than 4 million women become pregnant annually, millions more use oral contraceptives, or elect surgical interventions such as sterilization or induced abortion. Hundreds of women die because of pregnancy or childbirth, despite the fact that 75 percent of these deaths are preventable. Eleven infant deaths occur for every 1,000 live births, and again, a portion of these are potentially preventable.

CDC's reproductive health activity is targeted at public health problems associated with pregnancy, infant health, including maternal and infant morbidity and mortality, and fertility control. This activity includes epidemiologic studies and the development and maintenance of surveillance systems to measure the pattern and trend of reproductive health outcomes, and identifies ways to reduce health risks. CDC is also involved with the development and transfer of survey and evaluation technology to State and local health programs.

Epidemiologic field investigations of the medical consequences of fertility control methods used in family planning programs continue to be conducted by the Centers for Disease Control (CDC). Currently, there are approximately 40 million women in the United States who have used oral contraceptives at some time in their lives. However, the long- term effects of oral contraceptive use are still not completely known. CDC, in collaboration with the National Institute of Child Health and Human Development (NICHD), has completed the field work and data collection for a large scale epidemiologic study to answer questions related to oral contraceptive use. The major focus of this study is the association between oral contraceptive use and the risk of breast, endometrial, and ovarian cancer. Results of preliminary analyses were published indicating that women who have used oral contraceptives are approximately half as likely to develop an ovarian and endometrial cancer as women who have never used them and that, despite previous concerns, contraceptive use does not appear to increase a woman's risk of breast cancer. Analyses of the relationships of specific oral contraceptives and the three cancers showed similar results. An extension of this work is in progress to analyze the relationships of premenopausal estrogen use, alcohol use, and smoking to cancers of the breast, ovary, and endometrium.

The second major area of investigation related to medical consequences of fertility control is directed toward the study of early and late sequelae of tubal sterilization. This multicenter prospective study is following 8000 women after their operations. The second phase of the study, which has just commenced, will enroll a further 5000 women.

CDC, through an interagency agreement with NICHD, provided technical assistance to the School of Public Health, University of Puerto Rico, and the Puerto Rican Department of Public Health to support an assessment of family planning and maternal and child health in Puerto Rico. This project addresses fertility questions and family planning practices among Puerto Rican women and provides data for discerning fertility and family planning patterns in Puerto Rico. During fiscal year 1985, analysis of data was begun.

Epidemiologic analysis of the incidence and causes of pregnancy-related morbidity and mortality in the United States continues to be a major CDC activity. CDC analyses have shown that women who delay the initiation of childbearing to ever-increasing ages expose themselves to greater risk of death related to pregnancy. However, maternal mortality rates for women ≤35 years of age have declined approximately 50% from 1974-78 to 1982. Nevertheless, CDC estimates of maternal mortality based on the 7-State study of maternal mortality suggest that the 1990 Objectives for maternal mortality will probably not be achieved, particularly for black women. With respect to maternal morbidity, analyses from the hospital discharge survey revealed that 29% of hospital admissions for pregnancy (exclusive of ectopic pregnancy and abortion) and 4 million hospital days were due to nonroutine care. This burden of maternal morbidity requires further understanding to reduce its significant public health and economic impact.

CDC has collaborated with State Health Departments since 1969 to compile the only official national surveillance report on the number and characteristics of women obtaining induced abortions. The abortion rate (abortions per 1,000 women aged 15-44) continued its decline, first noted in 1981, through 1982 and 1983. Preliminary analysis of CDC abortion death investigations, begun in 1972, revealed that deaths attributed to complications of general anesthesia increased from 10.7% from 1972-79 to 29.4% from 1980-85. This is a result of greater reduction in other causes of abortion mortality.

Despite the importance of low birthweight as a risk factor of infant mortality, no national study of low birthweight-related infant deaths has been done since 1960. To provide such national data, all States, Puerto Rico, District of Columbia, and New York City shared data on standard tables for infants born during 1980 who died before their first birthday. CDC combined these with natality data from NCHS. Preliminary analyses have been completed of regional differences in birthweight-specific infant mortality and gestation-birthweight-specific infant mortality differences between blacks and whites. In May 1986 a National Infant Mortality Surveillance Conference will be sponsored by CDC, NICHD, AND HRSA to present analyses of these data, highlight strong State programs, and to provide representatives from State vital registrars and State MCH Directors to lay groundwork for future directions in infant health surveillance.

CDC provides training to Epidemic Intelligence Service (EIS) officers of the United States Public Health Service. Some individuals in the EIS Program, as well as other CDC career staff and international health professionals, are trained in an epidemiologic approach for evaluating family planning, maternal/child health, and population programs. EIS officers, career staff, public health advisors, or other trainees have been assigned to States to work in the area of family planning program evaluation.

CDC provided major technical and program assistance to 15 States during FY 1985. Domestic activities focused on management of family planning clinics. The Patient Flow Analysis (PFA) system, designed and developed by CDC, was modified for use with a microcomputer (IBM-PCXT) to enhance transfer of this system to State and local health agencies. A generic version of this system was also developed, which expands its use to other types of outpatient clinics. The original system has been used extensively to improve the efficiency of family planning clinics. The addition of simulation and generic programs will expand its usefulness to help agencies plan, modify, and evaluate family planning or other outpatient services as part of integrated health services or independently. Other highlights include:

- CDC staff assisted the Idaho Health Department conduct the first telephone survey devoted entirely to reproductive health issues, including contraceptive utilization, smoking among women of childbearing age, and breast-feeding. Costs for this type of survey were only 10 percent of those estimated for a household survey of comparable sample size.

- CDC completed the first multivariate areal analysis in 10 years to assess the impact of the Title X Family Planning Program on fertility of high risk groups. Program enrollment significantly lowered fertility of black teenagers and women aged 15-44. These effects were strongest among low-income women. In addition, it was found that the strongest predictor of program enrollment was the level of program activity, as measured by the number of program sites.

- At the request of DHHS Region X staff, CDC conducted a needs assessment workshop for the four States of Region X based on newly available data from the 1980 census and the 1982 National Survey for Family Growth.

- CDC also conducted four sessions on current contraceptive technology for U.S. clinicians and family planning program managers.

- The development of a Teenage Pregnancy Surveillance Report is underway, updating a surveillance report published earlier. This report will include the epidemiology of teen pregnancies in the United States.

III

OFFICE OF HUMAN DEVELOPMENT SERVICES

Office of Policy and Legislation

Title XX of the Social Security Act authorizes social services block grant funds to the 50 States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, and the Commonwealth of the Northern Mariana Islands for the provision of social services. Currently, for FY 1985, 33 States and eligible jurisdictions provide family planning services under their social services block grant program.

Family planning services are administered by the States and may include: information on the referral to available resources, personal counseling, medical services, referral for medical care and follow-up. OHDS does not track family planning activities in the States, as States, by virtue of the social services block grant legislation, do not have to meet any specific reporting requirements for services. Under the block grants, States have greater flexibility in determining what services to provide, the amount to be expended on services, eligibility for services, where these services will be provided, and who will provide them.

HEALTH CARE FINANCING ADMINISTRATION
MEDICAID FAMILY PLANNING

Title XIX provisions require States to provide medical assistance to categorically needy persons. In general, these are individuals who meet the financial eligibilty requirements of a related cash assistance program - Aid to Families with Dependent Children, Supplemental Security Income, or a State Supplement Program. If they choose to, States may also provide medical assistance to individuals who are not eligible for SSI or AFDC because they do not meet the income or resource standards, but who incur large medical expenses or have incomes slightly higher than cash assistance. These people are generally referred to as the "medically needy."

Family planning services were originally included in the Medicaid program as a State option. However, P.L. 92-603, enacted in October 1972, made coverage of family planning services for the categorically needy mandatory upon the States. This law also increased the rate of Federal financial participation for family planning services and associated administrative costs for both the categorically and medically needy to 90 percent (rather than the lower percentage authorized for most other Medicaid services).

Current law requires States to furnish family planning services and supplies, either directly or through arrangement with others, to Medicaid recipients of child bearing age (including minors who can be considered to be sexually active) who desire such services and supplies. The scope of family planning services varies among the States. Many States offer a comprehensive range of services to eligible individuals, while others limit family planning services: for example, to those furnished by or under the direction of a physician.

Title XIX regulations do not define family planning services with the exception of sterilization, which is specified as a Medicaid family planning service under strict Federal requirements for obtaining the informed voluntary consent of the individual under 21 who chooses the procedure.

In FY 1984, approximately $174.9 million was claimed by the States for family planning services. Of this amount, $51.6 million was spent for sterilization and $123.3 million for all other family planning related activities in FY 1984. Estimated family planning coverage (expenditures and recipients) under Medicaid for fiscal years 1984 through 1995 are contained in Tables HCFA-1 and HCFA-2.

TABLE HCFA-1

ESTIMATED FEDERAL, STATE AND LOCAL FAMILY PLANNING EXPENDITURES UNDER TITLE XIX: FY 1984 - FY 1990

(IN MILLIONS OF DOLLARS)

	FY 1984	FY 1985	FY 1986	FY 1987	FY 1988	FY 1989	FY 1990
Total Expenditures	$174.9	$185.6	$196.9	$207.9	$220.0	$231.9	$243.5
Sterilization Services	51.6	55.7	59.1	62.4	66.0	70.0	73.1
Other Family Planning Services	123.3	129.9	137.8	145.5	154.0	161.9	170.4

TABLE HCFA-2

ESTIMATED FEDERAL STATE AND LOCAL FAMILY PLANNING RECIPIENTS UNDER TITLE XIX: FY 1984 - FY 1990

(IN THOUSANDS OF PERSONS)

	FY 1984	FY 1985	FY 1986	FY 1987	FY 1988	FY1989	FY 1990
Total Recipients	1,576	1,625	1,659	1,699	1,740	1,782	1,825
Sterilization Services	110	113	116	119	122	125	128
Other Family Planning Services	1,466	1,512	1,543	1,580	1,618	1,657	1,697

1/ Actual amounts

2/ Actual recipients

DEPARTMENT OF HEALTH AND HUMAN SERVICES
POPULATION RESEARCH AND FAMILY PLANNING ACTIVITIES

Obligations FY 1983 - FY 1987
(dollars in millions)

				FY 1986			
	FY1983	FY 1984	FY 1985	Appropriation	After Sequestering	Revised Estimate	FY 1987
Total Department of Health & Human Services	$411.3	$460.2	$484.0	$498.4	$485.8	$460.4	$323.6
PUBLIC HEALTH SERVICE							
Office of the Assistant Secretary for Health							
Office of Population Affairs							
Adolescent Family Life Program	2/	2/	2/	2/	-	2/	2/
Family Planning Program	$174.1	$140.0	$142.5	$142.5	$136.4	$136.4	3/
Office of International Health 4/ (Special foreign currency program P.L. 480)	$ .1	$ .1	$ .1	$ .3	$ .3	$ .3	4/
National Institutes of Health							
National Institute on Child Health & Human Development	$102.0	$106.1	$114.7	$118.4	$113.7	$113.3	$113.9
Health Resource and Servuces Administration							
Maternal and Child Health Block Grant	5/	5/	5/	5/	-	5/	5/
Indian Health Service	2/	2/	2/	2/	-	2/	2/
Bureau of Health Professions	$ 35.1	$ 37.5	$ 39.4	$ 38.8	$ 37.1	$ 12.1	6/
Centers for Disease Control							
Total Public Health Service	$262.8	$285.3	$298.4	$301.5	$288.9	$263.5	$115.7
OFFICE OF HUMAN DEVELOPMENT SERVICE							
Office of Policy and Legislation	5/	5/	5/	5/	5/	5/	5/
HEALTH CARE FINANCING ADMINISTRATION							
Medicaid Bureau	$148.5	$174.9	$185.6	$196.9	$196.9	$196.9	$207.9 7/

Footnotes:

1 See appendix for explanation of tables.

2 Funding for family planning services cannot be determined.

3 Proposed for inclusion in Primary Care Block Grant.

4 All obligations are in excess foreign currency and are not included in the PHS or DHHS totals shown. No additional obligations are projected for FY 87.

5 Block grants to States. Funding for family planning services cannot be determined.

6 Due to a surplus of health professionals, Federal support is no longer required.

7 Projections for FY 87 are based on current law.

APPENDIX

Explanation of Tables

The financial data in these tables is intended to provide actual obligations for family planning activities and estimates for FY 86-87. For most agencies and programs the data represents an accurate accounting of such activities. The Office of Adolescent Pregnancy Programs and the Indian Health Service Program are unable to provide data on family planning activities since these are a small part of the many services provided.

Programs funded by HCFA and OHDS are legislatively mandated by Titles XIX and XX of the Social Security Act which are mainly State administered. The definition of family planning services varies among the States and has included, over the years, funds expended for abortion services and other family related health services which do not meet the universally used criteria for family planning services as established in Title X of the Public Health Service Act.

The Title XIX social services block grant (SSBG) legislation does not require States to report itemized administrative or service costs. Therefore, costs for family planning under the SSBG are not available.

HEALTH CARE FINANCING ADMINISTRATION

ABORTIONS

Part I - Background

HHS's Appropriations Acts have contained restrictions on the Department's funding of abortions since the Appropriations Act for FY 1977. HHS was enjoined by a Federal District Court from enforcing the FY 1977 restrictions until August 4, 1977. Consequently, the Department provided funding for all abortions which were covered under a State's plan that were performed through that date. The appropriations restrictions, commonly known as the Hyde Amendment restrictions, have governed HHS's funding of all abortions performed after August 4, 1977, except for those abortions performed during the period February 19, 1980, through September 19, 1980. Federal funding was available for all medically necessary abortions performed during that period under the criteria set forth by the District Court for the Eastern District of New York in the Harris v. McRae, 448 U.S. 297 (1980).

The following excerpts from instructions issued by HHS set forth the rules under which the Department has funded abortions performed after August 4, 1977, with its appropriations for FY 1977 through FY 1980.

1. For abortions performed after August 4, 1977, and for which funds appropriated by the appropriations act for FY 1977 or the continuing resolutions which appropriated funds through December 1, 1977, are used to pay the claim:

   > ". . . where the attending physician, based on his or her professional judgment, has certified in writing that the abortion is necessary because the life of the mother would be endangered if the fetus were carried to term."

2. For abortions performed after August 4, 1977, and prior to February 14, 1978, and for which funds appropriated by P.L. 95-205 (appropriations act for FY 1978) or P.L. 95-480 (appropriations act for FY 1979) are used to pay the claim:

   (a) Where the attending physician, based on his or her professional judgment, has certified in writing that the abortion is necessary because the life of the mother would be endangered if the fetus were carried to term;

   (b) where two physicians, based on their professional judgment, have certified in writing that severe and long-lasting physical health damage to the mother would result if the pregnancy were carried to term; or

(c) for the victims of rape or incest, when such rape or incest has been reported promptly to a law enforcement agency or public health service.

The Department will accept any reasonable interpretation of those provisions for abortions covered under paragraph 2.

3. For abortions performed on or after February 14, 1978, and prior to August 21, . 78, and for which funds appropriated by P.L. 95-205 or P.L. 95-480 are used to pay the claim:

(a) where a physician has found, and so certified in writing to the State agency, that on the basis of his or her professional judgment, the life of the mother would be endangered if the fetus were carried to term;

(b) where two physicians have found, and both certified in writing to the State agency, that on the basis of their professional judgment, severe and long-lasting physical health damage to the mother would result if the pregnancy were carried to term; or

(c) for the victims of rape or incest, if the State agency has received signed documentation from a law enforcement agency or public health service stating that:

(i) the person upon whom the medical procedure was performed was reported, within sixty (60) days of the incident, to have been the victim of an incident of rape or incest; and

(ii) the report included the name, address, and signature of the person who reported the rape or incest.

4. For abortions performed on or after August 21, 1978, and for which funds appropriated by P.L. 95-205 or P.L. 95-408 are used to pay the claim:

(a) where a physician has found, and certified in writing to the State agency, that on the basis of his or her professional judgment, the life of the mother would be endangered if the fetus were carried to term. The certification must contain the name and address of the patient;

(b) where two physicians have found, and certified in writing to the State agency, that on the basis of their professional judgment, severe and long-lasting physical health damage to the mother would result if the pregnancy were carried to term. The certification must contain the name and address of the patient. At least one of the two physicians must also certify that he or she is not an "interested physician." An "interested physician" is one:

(i) whose income is directly or indirectly affected by the fee paid for the performance of the abortion; or

(ii) who is the spouse of, or another relative who lives with, a physician whose income is directly or indirectly affected by the fee paid for the performance of the abortion; or

(c) for the victims of rape or incest, if the State agency has received signed documentation from a law enforcement agency or public health service stating:

(i) that the person upon whom the medical procedure was performed was reported to have been the victim of an incident of rape or incest;

(ii) the date of the incident;

(iii) the date of the report, which must be within sixty (60) days of the incident;

(iv) the name and address of the victim and the name and address of the person making the report (if different from the victim); and

(v) that the report included the signature of the individual who reported the incident.

The continuing resolutions which made funds available for FY 1980, P.L. 96-86 signed October 12, 1979, and P.L. 96-123 signed November 20, 1979, removed the exception which allowed payment for abortions in those instances where severe and long-lasting physical health damage to the mother would result if the pregnancy were carried to term when so determined by two physicians. Thus, Federal funding for abortions was prohibited except: (1) where the life of the mother would be endangered if the fetus were carried to term; and (2) for such medical procedures necessary for victims of rape or incest, when such rape or incest has been reported promptly to a law enforcement agency or public health service. Regulations implementing P.L. 96-86 were published at 42 CFR Part 441, on October 26, 1979. These regulations also applied to expenditures for abortions under P.L. 96-123 because the provision in that act governing abortions was similar to the one contained in P.L. 96-86.

On January 15, 1980, the District Court for the Eastern District of New York declared the Hyde Amendment unconstitutional insofar as it precluded payments for medically necessary abortions. That decision became effective on February 19, 1980, when the Supreme Court refused to extend a stay of the district court order. Federal funding then became available for all medically necessary abortions performed on or after February 19. The Supreme Court decision of June 30, 1980, reversed the district court's decision on the constitutionality of the Hyde Amendment. The petition for rehearing filed by the plaintiffs in the McRae case delayed the effective date of the Supreme Court's decision, leaving the district court order on payments for abortions in effect. The Supreme Court denied the appellee's petition for a rehearing in the McRae case on September 17, 1980, and the district court's order was vacated on September 19, 1980. Therefore, the availability of Federal funding for abortions performed after September 19, 1980, was subject to the FY 1980 Hyde Amendment restrictions; i.e., Federal funds under Medicaid were available only for abortions performed in life endangering circumstances and abortions performed in instances of promptly reported rape or incest.

On October 1, 1980, the President signed a joint resolution making continuing appropriations available for FY 1981 through December 15 or until the enactment of a subsequent appropriation. This resolution contained language which changed the conditions under which Federal funding was available for abortions under Medicaid. During FY 1980, Federal funds were available for abortions necessary for the victims of rape or incest when the rape or incest was reported to a law enforcement agency or public health service within sixty days. Under the FY 1981 resolution, Federal funds were available for abortions necessary for the victims of rape when the rape had been reported within seventy-two hours to a law enforcement agency or public health service. Federal funds were also available for abortions necessary for the victims of incest. There was no longer a reporting requirement for victims of incest. In cases of incest, Federal funding was available when the State agency had received a physician's written statement that the physician had been informed that the patient was a victim of incest. As in FY 1980, Federal funds continued to be available for abortions where the life of the woman would be endangered if the fetus were carried to term.

On June 5, 1981, the President signed the Supplemental Appropriations and Rescission Act, 1981. Under this act, FFP is no longer available for abortion claims paid after June 5, 1981, for victims of rape or incest. Federal funds continue to be available for abortions where the life of the mother would be endangered if the fetus were carried to term.

Subsequent Congressional measures through FY 1986 have continued to make Federal funds available for abortions where the life of the woman would be endangered if the fetus were carried to term. See P.L. Nos. 97-51, 97-92, 97-276 and 97-377, 98-107, 98-139, 98-619, 99-103 and 99-154.

Part II - Data on Medicaid Financed Abortions

Following the implementation on February 14, 1978, of regulations which resulted from the Hyde Amendment, a specific reporting procedure was developed for reporting information on Medicaid financed abortions. Data are reported quarterly by the States on the numbers of abortions and the allowable abortion-related expenditures. Data on the number of reported abortions for FY's 1978 - 85 are given in Table 1 while expenditure amounts are given in Table 2. The justifications for the reported abortions are shown in Table 3.

Since February 14, 1978, 59,782 Medicaid financed abortions have been reported by forty-seven jurisdictions through September 30, 1985. Total Medicaid expenditures, including Federal and State shares, for abortions have been $15,716,845 during the period February 14, 1978, through September 30, 1985. Eight jurisdictions (American Samoa, Arizona, Hawaii, Michigan, New York, the Northern Mariana Islands, Puerto Rico, and the Virgin Islands) have not claimed Federal funds for abortions. California has submitted claims for Federal Financial Participation (FFP) for abortions but has subsequently withdrawn these claims.

Of the 56 jurisdictions who reported for the period October 1, 1984 through September 30, 1985 (FY 1985), 24 jurisdictions claimed FFP under the Medicaid program for 874 abortions at a cost of $805,266, including both Federal and State shares. By comparison, in FY 1984 25 jurisdictions claimed FFP under the Medicaid program for 898 abortions at a cost of $865,711, including both Federal and State shares. All abortion claims are subject to review by regional office staff. All claims found not to meet the applicable Federal criteria for FFP will be either withdrawn by the State or disallowed by HCFA.

The Health Care Financing Administration has not collected information on the number of abortions provided to Medicaid recipients where the State did not claim FFP, or on the number of Federally financed Medicaid abortions prior to the implementation of the regulations on the Federal financing of abortions on February 14, 1978.

The abortion data in the attached tables reflect the most current information available as of December 12, 1985. Because States submit revised abortion claim data, the data contained in this report may differ with information contained in reports previously issued.

[illegible]

[illegible]

[illegible]

[illegible]

Materials Development

[illegible]

III. Consultative Services

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

staff [illegible] information needs and concerns, [illegible] prevention information programs. In [illegible] intermediary [illegible] to increase their [illegible] prevention efforts.

[illegible], together with NIDA, will attend approximately fifteen [illegible] during 1986 [illegible] on the [illegible] presentations in the past have been [illegible]. During 1986 NIDA will also [illegible]

[illegible]

[illegible] involving [illegible] movement of [illegible] spread of [illegible] It has [illegible] The [illegible]

[illegible]

[illegible]

IV. [illegible]

[illegible]

During the past year, NIDA continued to implement a collaborative project with the Department of Justice, Office of Juvenile Justice and Delinquency Prevention (OJJDP). The initiative, known as the Joint Venture on Violent Substance Abusing Youthful Offenders, initially encompassed three separate activities: (a) regional conferences on juvenile offenders with serious alcohol, drug abuse or mental health (ADM) problems; (b) continued funding of a University of Chicago survey on group shelter homes; and (c) the ADAMHA Joint Venture on Violent Substance Abusing Youthful Offenders.

Traditional treatment and prevention programs for violent substance abusing juvenile offenders [illegible] [illegible], the goals of this joint venture are to:

1. [illegible] to [illegible] drug abusing [illegible]

2. [illegible]

During [illegible]

[illegible]

V. Technology Transfer Services

[illegible]

A technology transfer program has also been initiated with the goal of increasing the ability of primary care providers to diagnose adolescent substance abuse and intervene early to prevent problems from becoming more serious. This is a collaborative effort involving the American Medical Association, American Psychiatric Association, American Academy of Pediatrics, American Academy of Family Physicians, National Association of Social Workers, American Nursing Association. The issues have been addressed and materials [illegible] for conferences, newsletters, journals and publications.

Recently, [illegible] technology transfer [illegible] in developing [illegible] and [illegible] and [illegible] [illegible]

[illegible] and [illegible] [illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible] goals

[illegible]

[illegible]

Technical assistance efforts [illegible] providers and [illegible] initiatives:

[illegible]

APPENDIX

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

NIDA has been actively participating on the PHS Executive Task Force on AIDS and has membership on the various subcommittees of the task force. We have recently testified at numerous congressional hearings on the topic and have responded to a steady stream of requests for technical assistance. To assure that a coordinated and responsive program is initiated, an AIDS Task Force has been established out of the Office of the NIDA Director. It is charged with coordinating activities, monitoring the progress of the overall effort and providing scientific and technical reports on NIDA's research and prevention activities. In addition, a new branch is being established in the Division of Clinical Research to launch an innovative clinical research program into the AIDS. A grant announcement has recently been issued to stimulate more research in this area.

A major goal of this research program will be to clarify the epidemiology and natural history of AIDS and infection among IV drug users. While it now appears clear that the transmission of the HTLV-III virus among IV drug users is primarily due to the sharing of needles, there are a number of questions about the extent to which the virus has disseminated and the role of drug use in the development of the disease. It has been noted that AIDS victims who are IV drug users contract different diseases and tend to die in a shorter period than AIDS victims without a history of IV drug use. This suggests that, while the initial exposure to the virus in drug users may be due to needle sharing, the subsequent development of AIDS and the course of the disease may be influenced by drug use. Over the past several years NIDA has developed evidence that drug use can impair immune functioning. Further research in this area will be important to determine whether drug use may increase the risk of developing AIDS or influence the course of the disease once it is contracted.

AIDS Prevention

NIDA's efforts to reduce the spread of acquired immunodeficiency syndrome (AIDS) in drug abusers are concerned with several special issues. Current efforts are focused on two major objectives: increasing the abilities of drug abuse counselors, health care professionals and criminal justice personnel and other professionals who come into contact with intravenous drug users to conduct AIDS prevention programs, and to diagnose and treat AIDS patients; and the development of effective prevention messages to reduce intravenous drug use.

Efforts to better inform professionals who come into contact with IV drug users on how to prevent and treat AIDS include the development of training manuals and audiovisual materials explaining the relationship between IV drug use and AIDS and how to diagnose and treat AIDS patients, sponsorship of workshops, and the provision of technical assistance to State and local organizations. Efforts to develop better prevention materials are especially important because of the high rate of transmission of AIDS between IV drug users and their apparently low access to normal prevention materials. Prevention materials are currently attempting to develop novel approaches.

such as targeting prevention messages toward the families or sexual partners of IV drug users, in attempting to improve the effectiveness of prevention programs.

In 1987, workshops will be conducted for persons associated with drug abuse service delivery, criminal justice administration, and health care to improve their understanding of HTLV-III infection, counseling of AIDS patients, and assisting AIDS patients in the health care system. Efforts will also be made to provide information on the precautions and strategies to be employed in working with HTLV-III positive patients in both residential and outpatient programs. NIDA will also work with national organizations representing State drug abuse agencies and local drug abuse treatment programs interested in the development of policies at the State and local levels.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Bureau of Health Professions

Drug Abuse

The Area Health Education Centers program had six grantees indicating activities in drug abuse with an estimated impact on [illegible] individuals. In FY 1985 a total of [illegible] was awarded to five of these six programs, with the largest award of [illegible] to the University of California-San Francisco.

In FY 1985 under the Family Medicine Residency program an award was made to [illegible] Hospital's [illegible] to support their training in drug abuse. University of Missouri - Kansas City's predoctoral and five graduate training programs indicated activity in drug abuse. Case Western Reserve's Establishment of Departments in Family Medicine grant program indicated providing substance abuse training.

The Baylor College of Medicine Physician Assistant training program received a total of [illegible] in the area of drug abuse in FY 1985.

In FY 1985 thirteen General Internal Medicine General Pediatrics Residency Training programs indicated that training in drug abuse would impact approximately [illegible] individuals. The Harvard Medical School received $3,216 for their drug training activities.

DEPARTMENT OF HEALTH AND HUMAN SERVICES REPORT ON POPULATION AND FAMILY PLANNING ACTIVITIES

A REPORT TO THE HOUSE COMMITTEE ON APPROPRIATIONS

Prepared by
The Deputy Assistant Secretary for Population Affairs
January 1986

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V. DHHS POPULATION AND FAMILY PLANNING ACTIVITIES

Obligations FY 1983 - 1987

I

INTRODUCTION

This report describes the population research, family planning, and population education activities of the Department of Health and Human Services.

Population research and family planning activities in the Department of Health and Human Services include support of service—making family planning information and services available and accessible; training—meeting the professional and the manpower needs in health, social services, and education; research—promoting and supporting research and research training in the biomedical and broad behavioral aspects of fertility, sterility, population dynamics and program implementation, and public education—increasing opportunities for public understanding of human sexuality, population education and information about family planning.

Under the Social Security Amendments of 1967 (Pub. L. 90-248), subsidized family planning services were made available through a variety of sources to some of those who could not afford them. The Social Security Amendments of 1972 (Pub. L. 92-603) required that family planning services be offered and provided promptly upon request to all recipients of Aid to Families with Dependent Children (AFDC) and of medical assistance (Medicaid). The Social Services Amendments of 1974 (Pub. L. 93-647) added a Title XX[1] to the Social Security Act (SSA). Under the Social Services Amendments of 1976, Pub. L. 94-401, States had the option of providing family planning services under Title XX to individuals regardless of their income. The major provisions of Pub. L. 93-647 remained in effect until Title XX was amended by Pub. L. 97-35, establishing the Social Services block grant program effective October 1, 1981[2].

The Family Planning Services and Population Research Act of 1970 (Pub. L. 91-572) established Title X of the Public Health Service Act, the major direct source of Federal support for family planning services programs.

[1] As initially enacted, SSA Title XX applied to the 50 States and the District of Columbia. Family planning social services for Guam, Puerto Rico, and the Virgin Islands were available under SSA Titles I, IV, X, XIV, and XVI.

[2] The participants in the Title XX Social Services block grant program are the 50 States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands and the Commonwealth of the Northern Mariana Islands.

Legislative Highlights

1. On January 2, 1968, the Social Security Amendments of 1967 (Pub. L. 90-248), which included the Child Health Act of 1967, were enacted. This act established categorical project grants for family planning services and required that not less than six percent of the monies appropriated for Maternal and Child Health under SSA Title V be available for family planning services. This same legislation required that under SSA Title IV-A, the AFDC program, family planning services were to be offered in all appropriate cases. Acceptance of such services was voluntary.

On December 24, 1970, the Family Planning Services and Population Research Act of 1970 (Pub. L. 91-572) was enacted, establishing Title X of the Public Health Service Act. This act was passed to assist in making comprehensive voluntary family planning services available to all persons desiring such services.

2. Title X program authorizations were extended by Pub. L. 93-45 in 1973, Pub. L. 94-63 in 1975, Pub. L. 95-83 in 1977, Pub. L. 95-613 in 1978, Pub. L. 97-35 in 1981, and Pub. L. [illegible] in 1985.

On October 30, 1972, the Social Security Amendments of 1972 (Pub. L. 92-603) were enacted. This Act made it mandatory to inform all recipients of AFDC of the availability of family planning services and to provide or arrange for services to all eligible persons voluntarily requesting them. The Act imposed a penalty of one percent per annum on the Federal share of AFDC funds on States which fail to provide these services to eligible persons desiring them. In addition, the Act increased the Federal share of matching for family planning services under Title IV-A--AFDC--to 90 percent from 75 percent. It also made family planning services a required service for all Title XIX--Medicaid--recipients, subject to a 90 percent Federal matching rate.

3. On January 4, 1975, the Social Services Amendments of 1974 (Pub. L. 93-647) were enacted. These amendments established SSA Title XX which placed major responsibility upon the States to develop their social services programs to be responsive to the needs of the citizens of each State. Title XX continued the requirement under (Pub. L. 92-603) that family planning services be offered and provided promptly to those AFDC recipients requesting such services. States had the option of providing family planning services on the basis of income eligibility status. In addition, States were required to provide three services to recipients of Supplemental Security Income (SSI) payments to aged, blind, and disabled. Family planning could have been one such service. The Federal share of matching was at the 90 percent rate.

6. On September 7, 1976, (Pub. L. 94-401) amended SSA Title XX, adding a provision that States may provide family planning services to individuals regardless of their income.

7. On November 10, 1978, the Health Services and Centers Amendments of 1978 were enacted. This Act established under Titles VI, VII and VIII within the Office of the Assistant Secretary for Health and in consultation and in coordination with the Deputy Assistant Secretary for Population Affairs, programs to prevent or reduce unwanted and repeat pregnancies among adolescents. These programs were to enable pregnant adolescents to obtain proper care and to become productive independent contributors to family and community life. In 1981, this program was incorporated into the Maternal and Child Health Block Grant.

8. On August 13, 1981, Congress amended Title XX of the Social Security Act by enacting social services block grant legislation under (Pub. L. 97-35). This block grant legislation became effective October 1, 1981. States were given greater flexibility in administering their social service programs than they had under the previous Title XX programs. The requirements with regard to eligibility for services and what services to cover are now left to the discretion of the States.

SUMMARY OF DHHS PROGRAM ACTIVITIES BY OPERATING AGENCY

PUBLIC HEALTH SERVICE

Office of the Assistant Secretary for Health

Office of Population Affairs

Supports delivery of family planning medical services, counseling and referrals.

Supports short-term training for family planning professional health personnel.

Supports family planning information and education activities.

Supports social research in the area of family planning service delivery.

Office of International Health

Policy development and coordination for international health programs and activities.

National Center for Health Statistics

Conducts surveys on fertility, family planning, and the reproductive health of American women.

National Institutes of Health

National Institute of Child Health and Human Development

Supports basic biomedical research on reproduction physiology and contraceptive development.

Supports social research on the causes and consequences of population structure and change, including factors affecting fertility and family planning.

Food and Drug Administration

Sponsors and monitors research on contraceptive safety.

Maintains a contraceptive reporting system.

Health Resources and Services Administration

Bureau of Health Care Delivery Assistance

Supports family planning services as well as consultation and technical assistance.

Indian Health Service

Provides family planning, information, and education services.

Bureau of Health Professions

Supports professional education programs for physicians and nurses.

Supports family nursing research.

Centers for Disease Control

Conducts epidemiologic field investigations of contraceptive methods and analysis of pregnancy-related morbidity and mortality.

Provides training for health professionals.

OFFICE OF HUMAN DEVELOPMENT

Office of Policy and Legislation

Supports family planning social and medical services, counseling and referral.

SOCIAL SECURITY ADMINISTRATION

Health Care Financing Administration

Bureau of Program Operations

Provides family planning services and supplies including sterilization services, to categorically needy persons through the Medicaid program.

II

PUBLIC HEALTH SERVICE

Office of the Assistant Secretary for Health

Office of Population Affairs

The Office of Population Affairs (OPA), under the direction of the Deputy Assistant Secretary for Population Affairs (DASPA), administers the Title X Family Planning Program and the Title XX Adolescent Family Life Program. In addition to these program administration activities, the DASPA advises the Secretary, through the Assistant Secretary, on policy and new legislation; participates in legislative and fiscal planning; and prepares reports on departmental and inter-departmental activities for the Secretary and the Congress. The DASPA also works in cooperation with other Federal agencies, as well as with other concerned organizations, in the areas of population research and family planning services, training and education.

Within the OPA, the Office of Family Planning administers family planning activities authorized under the "Family Planning Services and Population Research Act of 1970" (P.L. 91-572), which established Title X of the Public Health Service Act. Title X authorizes project grants for voluntary family planning services, and grants and contracts for continuing professional education for family planning services personnel, for services delivery improvement research, and for family planning information and education. Categorical project grants under Title X of the PHS Act represent the major Federal source of direct funding for family planning services.

The broad purposes of Title X are stated in the law as follows:

1. To assist in making comprehensive voluntary family planning services readily available to all persons desiring such services;

2. To improve administrative and operational supervision of family planning services;

3. To enable public and private nonprofit entities to plan and develop comprehensive programs for family planning services;

4. To develop and make readily available information (including educational materials) on family planning to those desiring such information;

5. To evaluate and improve the effectiveness of family planning service programs; and

6. To assist in providing trained personnel needed to effectively carry out family planning programs.

The primary target group for Title X family planning services is the estimated [illegible] million low income women at risk of unintended pregnancy. An estimated 4 million of these women receive services from organized family planning programs—over 3 million from Title X funded programs. Another [illegible] million low-income women receive services from private physicians.

The Office of Family Planning allocates Title X service funds to the ten DHHS Regional Offices, which in turn allocate these funds among their [illegible] grantees, request and approve applications for Title X service grants, and monitor grantee performance. A Regional Program Consultant for family planning serves as coordinator for family planning activities in each Region. There are currently 4,[illegible] family planning clinics funded by Title X.

The primary objectives of the program have been to continue to provide high quality family planning services, to improve the efficiency and effectiveness of family planning projects, and to encourage the involvement of the family in the provision of family planning services. Staff development programs, information and education activities, and service delivery improvement research have been directed to support the attainment of these objectives.

Title X training programs are designed to provide personnel with skills, knowledge, and attitudes necessary for the effective delivery of family planning services. Training is provided in structured and non-structured settings and includes in-service education, staff development, and continuing education activities that are innovative, self-paced, self-instructional or mediated with newer technological advancements in the learning field. The current national priority areas are 1) family involvement, 2) program management, 3) clinic management, 4) infertility, 5) natural family planning, and 6) counseling and client education.

In Fiscal Year 1985, ten general training grants, one in each of the DHHS regions, were awarded. These grants are aimed at providing training for all personnel who are employed in Title X funded clinics such as managers, mid-level providers, professional and technical staff and clerical/receptionist staff. The five obstetric/gynecology or women's health care nurse practitioner programs train registered professional nurses who are employed in family planning clinics to become nurse practitioners. Approximately [illegible] nurse practitioners were trained for Title X clinics in Fiscal Year 1984. Nurse practitioners provide 80-[illegible] percent of all encounters in family planning clinics. They are an essential part of the family planning services delivery system because they increase a clinic's capacity for providing high quality, cost-effective health care services to more clients. All Title X funded nurse practitioner training programs are nationally accredited by the American Nurses' Association. Since the beginning of the training program in [illegible], Title X funded training projects have produced more than [illegible] nurse practitioners.

The major activities supported under the Title X information and education program include the operation of the National Clearinghouse for Family Planning Information and the development of information and education materials for family planning clients and clinic staff. During [illegible], the Clearinghouse distributed over [illegible] pieces of material including patient education pamphlets, information and education bulletins for clinic staff and bibliographies. Two pamphlets are being produced for parents and adolescents to encourage parent/child communication about sex and sexual relations. Because of its usefulness in discouraging premarital adolescent sexual relations and the number of requests, the pamphlet, "Most Teens Are Saying 'No,'" is being reprinted. Another pamphlet is being produced to explain the modern methods of natural family planning. For clinic staff an education and information bulletin written by CDC staff was produced on the use and effectiveness of the contraceptive sponge. Currently under way are two bulletins on (1) literacy levels of family planning client information materials and (2) pelvic inflammatory disease and infertility. The single most requested client information and education pamphlet, "Family Planning Methods of Contraception," which was first developed in [illegible], is being updated to include the most recent data on how contraceptives work, effectiveness, and possible complications.

The focus of the Service Delivery Improvement (SDI) Research Program continues to be enhancement of the delivery system, particularly at the clinic level. In addition to direct technical assistance efforts in this regard, the SDI research program funded projects to obtain knowledge needed by family planning service providers to better understand service delivery processes and how such processes may be influenced in the desired direction. Nine new and five continuation research grants were supported, covering an array of topics -- male involvement in family planning, evaluations of family planning counseling and educational strategies, lessons for improving family planning services from other developed countries, sources of clinics' failures to reach underserved clients, and family planning needs of specialized populations, e.g., the child welfare population. Two SDI research contract awards were also made: 1) to make available computer-readable data on family planning in the form of a data archive and 2) to analyze national data on contraceptive method efficacy in pregnancy prevention.

Plans for procedural changes in the SDI research grants program were developed to increase efficiency and improve quality of research proposals. The well-respected NIH peer review component was maintained while a standing program announcement was developed and routinized dates for proposal receipt were established, replacing the ad hoc review procedures that had been utilized previously.

INTERNATIONAL ACTIVITIES

The Office of International Health (OIH), a staff office to the Assistant Secretary for Health, has primary responsibility in the Public Health Service for overall policy guidance, on behalf of the Assistant Secretary for Health, and coordination of PHS international health programs and activities. In this role, OIH promotes appropriate involvement in activities of mulilateral organizations (e.g. the World Health Organization) and in bilateral progams of the United States Government.

Each of the PHS Agencies engaged in population and family planning activities domestically has also been involved, at one time or another, in population and family planning activities internationally. The PHS compoents most directly involved in international population and family planning matters are the Center for Population Research of the National Institute of Child Health and Human Development, NIH, and the Center for Health Promotion and Education of the Centers for Disease Control.

International involvement takes several forms--participation in programs and activities of multilateral organizations; research grants and contracts, emcompassing biomedical research, development of new products and demographic and sociological studies, with U.S. and foreign institutions; and collaborative projects conducted under binational agreements and programs. The PHS Agencies also provide technical assistance to other countries on population and family planning programs in cooperation with the U.S. Agency for International Development (AID).

Cooperative and collaborative efforts have continued with the World Health Organization (WHO) regarding the development of safe and efficacious methods of fertility regulation. These activities range from mutual consultations to product development. Staff of the Center for Population Research, NICHD, served as consultants to the WHO Special Programme of Research in Human Reproduction and its Committee on Methods for the Regulation of Fertility; and the Committee on Post-Ovulatory Methods. They also participated on the WHO Task Force on Contraceptive Safety and in a Steering Committee Meeting of the WHO Task Force on Behavioral and Social Determinants of Fertility Regulation. Staff of the Center attended a WHO meeting to exchange information concerning recent research accomplishments involving contraceptive development and to discuss the identification of agencies and collaborative programs that provide support in this field. In addition, the Center has continued to undertake extensive screening of chemicals synthesized by WHO, which, in turn, has done some of the clinical testing of modalities developed either by the Institute alone, or through mutual funding. For the past two year, a CPR official has been detaid to the WHO Special Program of Research, Development, and Research Training in Human Reproduction, as Senior Medical Officer.

CRP staff continued to cooperate with and participate in meetings of the European Medical Research Council's (EMRC) Advisory Subgroup on Human Reproduction. The Advisory Subgroup identifies areas for cooperation within Europe and between Europe and the United States on research in reproduction. It also interacts with the pharmaceutical companies in order to obtain information about any of their research projects which might have a bearing on human reproduction.

Cooperation has continued under two important binational agreements -- those with the People's Republic of China and India. Scientific information, experimental reagents, antisera, standards, and radioimmunoassay kits have been exchanged with Chinese scientists, as a result of the visit by the U.S. Delegation on Reproductive Physiology and Family Planning Techniques to the People's Republic of China in June 1981 and subsequent follow up discussions. CPR, NICHD staff comprised three of the four members of the U.S. Delegation, which made the first visit to China for this new scientific area under the U.S.-P.R.C. Health Protocol. The program with India has been quite active and effective since 1978, with the establishment of the Indo-U.S. Joint Working Group on Reproductive Physiology. Staff of CPR, NICHD, and of the National Institute of Health and Family Welfare in New Delhi are jointly organizing and presenting a technical workshop on Preimplantation Development of Embryos to be held in New Delhi in March 1986. This is in follow up to the Fourth Indo-U.S. Workshop on Reproduction and Contraception Research, which was held in August 1984 at NIH, under the auspices of the Indo-U.S. Subcommission on Science and Technology and the Indian Council for Medical Research. The Center is sponsoring a joint research project between Indian and U.S. scientists on blastocyst metabolism as an outcome of a previous Indo-U.S. Workshop. In addition, CPR is supporting collaborative research on immunological approaches to fertility regulation for men and women under the Indo-U.S. Science and Technology Initiative, which was announced by President Reagan and Prime Minister Indira Gandhi in 1982.

The Fogarty International Center, NIH, held an international conference in June 1985, on "Immunological Approaches to Contraception and Promotion of Fertility." The regulation of a vital process, such as reproduction, by internally produced antibodies has far-reaching implications. The symposium was organized by Dr. G.P. Talwar, Director of India's National Institute of Immunology, who was serving as a Fogarty Scholar-in-Residence at NIH.

The Centers for Disease Control continued to cooperate effectively with the Agency for International Development under a reimbursable services agreement. CDC staff provide logistics assistance, perform contraceptive requirements analyses, conduct program evaluations, evaluate and collect program data, provide information and data to AID-assisted countries, and assist in the implementation of recommendations and innovative program strategies. During FY 1985, assistance was provided to Brazil, the Caribbean Regional Development Office (Barbados), Colombia, Costa Rica, El Salvador, Guatemala, Haiti, Honduras, Jamaica, Mexico, Panama, Peru, Bangladesh, India, Indonesia, Pakistan, Thailand, Turkey, Botswana, Ghana, Kenya, Lesotho, Mauritius, Nigeria, and Zimbabwe, among others.

The National Center for Health Statistics (NCHS) continued to cooperate with AID to improve vital statistics systems in developing countries. Work with Jamaica continued during 1985. Improvements in vital statistics systems will facilitate efforts of countries to make population projections and evaluate their family planning programs.

The Office of Population Affairs made two awards which had international components. One award was for a project to study family planning in 22 developed countries, with special emphasis on England, Wales the Netherlands and Sweden. The purpose of this project is to learn how family planning services for adults in the United States can be delivered more effectively and efficiently through examination of the experiences of other developed nations.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

FAMILY PLANNING INFORMATION

The major data activity of the National Center for Health Statistics (NCHS) in the area of family planning is the National Survey of Family Growth (NSFG). This survey is designed to provide national statistics on the fertility, family planning and reproductive health of American women in the childbearing ages.

The First and Second Cycles of the survey were conducted in 1973 and 1976, respectively, and were based on samples of women 15-44 years of age; never married women were excluded. More than 80 NCHS reports and journal articles from Cycles I and II have been published and public use data tapes for further scientific research were released.

Interviews for Cycle III were taken in late 1982 and early 1983 and the sample included women 15-44 years of age regardless of marital status. In 1984, a public use data tape, for scientific research, was released and an overview of the principal findings published. Reporting of Cycle III findings continued throughout 1985 with the publishing of a Series 2 report on the sample design, five Advance Data reports, and several journal articles on such topics as infertility, contraceptive use, and pregnancy rates. Further results from Cycle III will be released throughout 1986. Two journal articles, one on religion and fertility, the other on adoption, are already scheduled for publication. Four NCHS Series 23 reports -- on contraceptive use, family planning services, fecundity and infertility, and reproductive unions -- are in advanced stages of preparation, with other reports and articles in earlier stages or planned.

Planning for Cycle IV is well underway with the pre-test scheduled for September 1986, and the main survey scheduled for April through November 1987. A representative sample of about 11,000 women 15-44 years of age will be interviewed.

The NSFG addresses a wide range of specific topics related to the reproductive experience and health of the population:

- o pregnancies and their outcomes, including those to teenagers;
- o the extent to which pregnancies were planned and intentions for future births;
- o the extent of impaired fecundity, infertility and other reproductive health problems;
- o contraceptive method preference and the comparative use-effectiveness of various methods;

- trends in the use and discontinuation of specific contraceptive methods;
- use of family planning, infertility and prenatal care services (both public and private);
- use of day care services, and the work experience and occupation of mothers in relation to their childbearing.

The survey provides important baseline and evaluation data for a variety of health programs which are reflected in the funding support given by such agencies as the National Institute for Child Health and Human Development and the Office of Population Affairs. The results of Cycle III and Cycle IV will provide the principal data for monitoring the specific decade objectives for family planning in the Department's program for "Promoting Health and Preventing Disease."

NATIONAL INSTITUTES OF HEALTH

National Institute of Child Health and Human Development

FAMILY PLANNING AND POPULATION RESEARCH

The National Institute of Child Health and Human Development (NICHD) has the primary responsibility for the research programs in the population sciences of the Department of Health and Human Services. Section 448 of Title IV of the Public Health Service Act as amended by P.L. 99-158 authorizes the Institute to conduct and support "research, training, health information dissemination, and other programs with respect to maternal health, child health, mental retardation, human growth and development, including prenatal development, population research, and special health problems and requirements of mothers and children." Section 1004 of Title X of the Public Health Service Act, as extended, authorizes the Department of Health and Human Services to award grants and contracts for "research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population."

The Center for Population Research (CPR) of the National Institute of Child Health and Human Development is responsible for the primary Federal extramural program in population research. Support is provided through grants and contracts for:

- -Fundamental biomedical research in the reproductive sciences relevant to the problems of human fertility and infertility.
- -The development of safe and efficacious methods for fertility regulation.
- -The evaluation of the benefits and risks of current contraceptive methods.
- -Demographic and behavioral sciences research on the causes and consequences of population structure and change.

The support of population research and research training includes the funding of programs for institutional development and population research manpower development. In addition, the Center facilitates the coordination of Federal population research programs, enhances the communication of research information in the population sciences, and advances international cooperation in population research.

The following describes some of the activities and some examples of recent findings of research supported by CPR, NICHD.

Reproductive Sciences

The NICHD program in the reproductive sciences--in medicine, endocrinology, genetics, immunology, and developmental biology--supports a basic science research base of sufficient quality, scope, critical mass and diversity to facilitate: 1) the alleviation of human infertility; 2) the amelioration or cure of human reproductive diseases and disorders; 3) the development of healthy embryos; and 4) the discovery of new leads for the development of improved methods of fertility regulation.

An NICHD grantee at Columbia University, Dr. Robert Canfield, has been evaluating a new immunological assay that could be used to discriminate between successful and failed pregnancies at short post-conception intervals. The test detects a hormone produced by the placenta, human chorionic gonadotropin (hCG), which stimulates the ovary to increase its hormone production that is necessary to maintain pregnancy. In his study of a group of 30 women attempting to become pregnant, Dr. Canfield found that the new immunoradiometric assay (IRMA) detected hCG at concentrations 100 times lower than a previously used test and also detected pregnancies an average of four days sooner. IRMAs enhanced sensitivity and specificity thus enabled Dr. Canfield to determine the occurrence and loss of very early pregnancies that otherwise would have been undetectable. Little is currently known about the extent or causes of pregnancies lost before their existence can be recognized. The effectiveness of the new test suggests that it will be a useful tool for clinical and epidemiological studies designed to quantify and evaluate the basis of early pregnancy failure.

Contraceptive Development

The contraceptive development program supports clinical trials and laboratory studies aimed at developing improved methods of fertility regulation for both men and women which are safe, effective, reversible, and acceptable to the public. This research involves: 1) the development of new drugs which can potentially regulate fertility in both sexes; 2) the development of improved methods of drug administration; 3) the improvement of barrier methods of contraception; and 4) the provision of research resources.

Significant progress has been made in overcoming one obstacle to developing a hormonal method of male contraception: the need for a long-acting male hormone preparation that would have to be used as replacement therapy for the maintenance of libido. The currently available products have to be injected about every two weeks; for this and other medical reasons, they are of limited utility. Under NICHD contracts, an extensive biological screening program has been carried out by Dr. Rehan Naqvi at the Mason Research Institute in Worcester, Massachusetts using rats and by Dr. Dan Dalgard at Hazelton Laboratories America, Inc. in Vienna, Virginia using monkeys. These efforts have resulted in the identification of a new derivative of the male sex hormone, testosterone, that is much longer acting than current preparations and will require injections at intervals of only two or three months. In addition to its use as a potential component of a male contraceptive, this new drug would be useful for the treatment of men who suffer from testosterone deficiency.

Contraceptive Evaluation

The contraceptive evaluation program supports: 1) clinical trials; 2) large health surveillance cohort studies; and 3) prospective and retrospective epidemiological studies that seek to associate suspected measurable health and fertility effects (risks and benefits) with the use of oral contraceptives, intrauterine devices, barrier methods, and sterilization procedures.

Data from the second National Health and Nutrition Examination Survey, conducted under an interagency agreement by the National Center for Health Statistics of the Department of Health and Human Services, have been analyzed to assess the cardiovascular risk profile of oral contraceptive (OC) users and nonusers in the United States. The data indicate that eight percent of U.S. women who use OCs have three or more established risk factors for atherosclerotic heart disease, such as smoking, elevated total cholesterol, or obesity, while they are users of contraceptive pills. In addition, over 45 percent of OC users have at least one risk factor for heart disease, the most common of which is smoking.

Demographic and Behavioral Sciences

The demographic and behavioral sciences program supports research concerned with factors governing variations in the growth, distribution and characteristics of people and the impact of population change on the health and well-being of individuals, families, and society as a whole. This involves studies on the causes and consequences of the three components of population change: fertility, migration, and mortality.

Dr. Kristin Moore, a grantee at Child Trends, Inc. in Washington, D.C., has been assessing the effects of teen parenthood on the offspring's school-related achievements using data from the National Survey of Children conducted by her organization. The most important predictor of the child's academic progress was found to be the mother's own educational attainment. The higher the level of schooling of the mother, the better her child tended to be in both vocabulary score and grade progression. Children of mothers who were in school at the time of pregnancy or who dropped out and returned to complete additional schooling, did much better than the children of mothers who had dropped out of school before pregnancy and had not returned. Among children of women who delayed childbearing past the high school years, the children of mothers who dropped out of high school before graduation were also found to have lower vocabulary scores.

Future Directions of Family Planning and Population Research

Reproductive Sciences

Research in the reproductive sciences will be supported in the following areas: reproductive medicine, including studies concerning the treatment of infertility in women and men, the alleviation of human reproductive diseases and disorders, the precise monitoring and effective prevention of ectopic implantation of embryos and pregnancy wastage, and the relationship of pelvic inflammatory disease to reproductive failure; reproductive endocrinology, including the determination of the structure and the synthesis of putative new reproductive hormones, studies on the regulation of gene expression by sex steroid hormones, clarification of the mechanism of action of reproductive hormones; and elucidation of the elements of endocrine signals that are involved in the etiology of reproductive disease and health; reproductive genetics and immunology, including studies to determine the genetic basis of reproductive disorders, to detect or quantitate reproductive hormones or reproductive tract tissue secretions of importance in the diagnosis of reproductive disorders, to evaluate their therapeutic efficacy, and to investigate the potential for fertility regulation by immunologic methods and the immunologic factors associated with infertility; and developmental biology of reproduction, including studies of the manner in which specific genes are involved in preimplantation embryo development; of the more readily visible results of gene activity, such as fertilization, cell division, early development of the placenta, and implantation; and of the techniques for fertilization and embryo transfer.

Contraceptive Development

Research in contraceptive development will be supported in the following areas: clinical trials, including studies of the potential of synthetic analogs of the hypothalamic releasing hormone, luteinizing hormone releasing hormone (LHRH), for fertility regulation in men and women, evaluation of long-acting implants and injectables, investigation of new steroid combinations for male contraception, exploration of improved barrier methods including the cervical cap and the diaphragm, and testing of new oral contraceptives; drug development, including the synthesis and biological testing of LHRH analogs and the screening of new compounds for potential fertility regulation in men or women; drug delivery systems, including efforts to improve methods of contraceptive drug administration for both steroids and peptides; and barrier methods, including the evaluation of new spermicidal agents.

[illegible]

Justification	Total	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Total Abortions Reported	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Total with Justification Identified	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Life of Woman Endangered	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Severe and Long Lasting Damage to Health of Woman	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Rape or Incest	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Medically Necessary	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Justification Unknown	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

1. Data for this report are taken from the [illegible]
2. The continuing resolutions, which [illegible] the Hyde Amendment restrictions, [illegible] or disallowed by HCFA if they do not meet the [illegible]
3. Under the Supplemental Appropriations and Rescission Act, [illegible] on the basis of rape or incest [illegible]
4. These abortions were performed between [illegible] with F.Y. 1981 or 1982.

Part III

Results of FY 1985 State Assessment Reviews of Medicaid Abortions

During fiscal year 1985, the following States were reviewed to assess compliance with Federal regulations related to Medicaid payment for abortions.

Vermont
Virginia
Pennsylvania
Delaware
Washington, D.C.
South Carolina
North Carolina
Mississippi
Florida
Kentucky
Alabama
Tennessee
Nevada
Oregon

In all but one of these States necessary procedures were followed and federal payments were properly limited to situations where a physician certified in writing that the mother's life was endangered. The only major problem identified involved the State's processing system which needed to be strengthened.

This information includes results of reviews of claims from FY 1985 and prior periods. Therefore data on the number of abortion claims for each State reported in this section may not correspond to data reported in Part II.

Results of State Assessment Reviews of Medicaid Abortions

Vermont

A review of the two abortion claims where the mother's life was endangered showed the necessary certification/documentation.

Virginia

The State's procedures for payment of abortion claims were reviewed for compliance with federal regulations at 42 CFR 441.200. The findings revealed that procedures require that abortion claims include a signed certification by the physician that the life of the mother is endangered if the fetus is carried to term. The State has designated certain abortion procedure codes which suspend a claim for review.

For each calendar quarter, the State's claims processing system is designed to capture a total amount of dollars spent on abortions. There were no paid abortion claims for the review period.

Pennsylvania

The State claims FFP only in those cases where the life of the mother would be endangered if the fetus was carried to term.

Three sets of invoices for abortion procedures for which FFP was claimed were reviewed. In all 3 cases the physician indicated that the mother's life would be endangered if the fetus was carried to term. Manuals, handbooks, and bulletins were reviewed and found to contain adequate explanations of abortion requirements.

Delaware

For abortion procedures the State claims federal financial participation only in those cases where the life of the mother would be endangered if the fetus were carried to term.

The State does not permit payment for abortions in any other situations. In an FY 1981 bulletin all requirements for provider completion of abortion invoices and attachments were spelled out. In addition, specific training is given to providers new to the program.

The State has made no FFP claims for abortion services nor were any abortion invoices submitted for payment by providers during the review period.

Washington, D.C.

The District of Columbia does not claim federal financial participation for abortion procedures.

South Carolina

The State provides instruction to providers in order for them to comply with Federal abortion requirements. All requirements for the funding of abortion and abortion-related services were met.

North Carolina

The State has provided guidelines for use of FFP in payment for abortions. The State provides instruction to providers so that they are able to comply with State and Federal abortion requirements.

All requirements for the funding of abortion and abortion-related services were met.

Mississippi

The State has provided instruction and guidelines to providers in order for them to comply with Federal regulations.

Florida

The review indicated that the State claimed Federal Financial Participation for only those abortions which met all Federal requirements.

Kentucky

This State met all federal requirements for the funding of Medicaid abortions.

Alabama

Instructions were issued to providers in order to educate them with Federal abortion requirements.

All federal requirements were met for the funding of abortions.

Tennessee

Based on the FY 1985 review, all requirements for the funding of abortion and abortion-related services were met.

Nevada

The State only pays for induced abortions when a physician has found and certified in writing to the Medicaid agency that the life of the mother would be endangered if the fetus were carried to term.

During the review period, the State paid for one induced abortion which was life threatening. Two other claims were pulled that had originally been miscoded, but no federal matching was claimed for these procedures.

Oregon

The FY 1985 review found that 52 of 53 abortion cases were performed on the basis of an unwanted pregnancy.

The regional office recommended that the State strengthen its procedures for processing abortion and abortion-related claims to ensure those procedures that are performed for other than the life of the mother would be excluded from FFP.

GENETIC DISEASES
Obligations

	1983	1984	1985	1986 Appropriation	1986 Available after Sequestration	1986 Revised Estimate	1987 Estimate
Public Health Service:							
National Institutes of Health:							
National Institute of General Medical Sciences	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	88,816,000
National Heart, Lung, and Blood Institute	[illegible]	42,659,000	[illegible]	[illegible]	[illegible]	43,400,000	42,000,000
National Institute of Arthritis and Musculoskeletal and Skin Diseases	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	5,550,000	5,350,000
National Institute of Diabetes and Digestive and Kidney Diseases	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	27,500,000	26,800,000
National Institute of Neurological and Communicative Disorders and Stroke	[illegible]	31,247,000	[illegible]	[illegible]	[illegible]	[illegible]	50,013,000
National Institute of Allergy and Infectious Diseases	1,676,000	1,259,000	[illegible]	[illegible]	2,090,000	2,082,000	1,942,000
National Institute of Child Health and Human Development	41,970,000	51,306,000	62,301,000	64,200,000	61,400,000	61,200,000	61,600,000
National Eye Institute	21,633,000	22,577,000	21,701,000	28,900,000	28,500,000	27,700,000	27,700,000
National Institute on Aging	1,308,000	2,110,000	3,636,000	4,026,000	3,854,000	3,778,000	3,710,000
Division of Research Resources	16,000	18,000	21,000	21,000	20,000	20,000	15,000
Total, NIH	165,546,000	192,271,000	226,146,000	245,539,000	234,794,000	231,348,000	228,046,000

NATIONAL INSTITUTES OF HEALTH

National Institute of General Medical Sciences

GENETIC DISEASES

About 5 percent of the U.S. population suffers from some form of [illegible] genetic disorder. Thirty percent of all hospitalized children are treated for diseases of genetic origin. The economic impact is considerable, [illegible] 15 to 20 percent of all health care costs are for the treatment of genetic diseases. By one estimation, it costs the Nation almost $1 billion each year to treat and care for victims of Down's syndrome alone—a disorder that afflicts 1 out of every [illegible] births.

To better understand genetic disorders, scientists study normal as well as abnormal genetic processes. To this end, the National Institute of General Medical Sciences (NIGMS) Genetics Program supports [illegible] from classical [illegible] genetic [illegible] diseases. NIGMS has [illegible] research that underlies [illegible] significant contributions to [illegible] as well as [illegible] itself.

[illegible] the means to get [illegible] as well as providing [illegible] developments [illegible] the production of [illegible] scientists to [illegible] markers associated with a particular gene, [illegible] that should bring gene [illegible] target DNA molecules [illegible] for the first time. [illegible] researchers to perform [illegible] difficult or impossible, [illegible] with which to use these [illegible].

[illegible] to analyze and manipulate the genetic makeup of [illegible] previously [illegible] of heredity. [illegible] the result of [illegible] many of [illegible] recent advances [illegible] for the future [illegible] new clinical findings that [illegible] treatment, cure, or even prevention of genetic diseases.

The Not-So-Universal Genetic Code

In March of this year, NIGMS grantee Dr. John Preer, Jr., at Indiana University in Bloomington reported the startling discovery of an organism that does not follow all the genetic rules previously assumed to operate for every living creature on earth. Two researchers at the Center for Molecular Genetics in France described similar results at the same time. Now, several other laboratories have published related findings.

Scientists know that all living organisms contain DNA and/or RNA (the language of heredity). Genes are sections ("words") of DNA that dictate the characteristics of an organism. The translation of these "words" into their meanings (or protein products) is governed by rules in much the same way that writing a sentence is governed by rules of syntax and grammar. Prior to the recent discovery by Dr. Preer's laboratory and that of the French team, scientists believed that the system by which information held in DNA and RNA is translated was the same for all living organisms.

This information--the "genetic code"--is contained in the precise arrangement of five subunits, or bases, abbreviated C, G, A, T, and U. A group of three of these bases (called a codon) specifies a single "command" for the translation of DNA, such as coding for a specific amino acid (protein building block) or for protein synthesis to stop. Scientists had assumed in the past that the genetic code was universal and that the same arrangement of bases held the same information regardless of the organism in which it was found. Indeed, the majority of organisms do share a common genetic code--this is what makes recombinant DNA research successful. But Dr. Preer has found one organism that deviates from the common code, so the belief that the code was universal must be changed. It appears that a few other related organisms also deviate from the common genetic code.

Dr. Preer has been studying *Paramecium tetraurelia*, a member of a group of single-celled organisms called ciliated protozoans, to learn more about the genes responsible for the proteins on its surface. He found that the gene sequences that are the blueprints for these proteins contain the codons TAA and TAG, which in other organisms signify "stop making protein." In *P. tetraurelia*, however, these codons appear to code for the amino acid glutamine. Through a series of experiments designed to check his results, Dr. Preer and his colleagues concluded that the evidence indeed indicated that in this ciliated protozoan TAA and TAG are the DNA code words for glutamine, rather than for "stop." Further studies in this area are expected to provide new clues about the evolution of the genetic code.

"Metallic" Molecules Illuminate DNA Structure

Scientists' understanding of the chemistry of DNA and aspects of its three-dimensional structure is in its infancy. One scientist who is [illegible] this field [illegible] is Dr. Jacqueline Barton, [illegible] at Columbia University in New York City. [illegible] properties of various metals to [illegible] that are [illegible] DNA.

[illegible] in many different shapes, [illegible]

[illegible]

[illegible] DNA [illegible]

[illegible]

Master [illegible] Development

[illegible]

For development to proceed [illegible] developmental events [illegible] must be [illegible] the DNA of [illegible] may include as many as [illegible] genes, [illegible] regulated individually. [illegible] existence of "master switches" in development. [illegible] discovery of homeotic genes, which function as one type of "master switch."

Homeotic genes control the location of developing body parts. Mutations of these genes transform one type of structure, such as antennae, into another normally found on a different body segment, such as legs.

A major advance in our understanding of homeotic genes occurred when NIGMS grantees Dr. Thomas Kaufman at Indiana University and Dr. David Hogness at Stanford University in California determined the exact locations of the two major groups of these genes on a fruit fly chromosome. This groundwork led to the recent discovery that homeotic genes have one characteristic section of DNA in common. This section has been named the "homeo box" and is now known to exist in yeast, beetles, worms, frogs, chickens, mice, and humans as well as fruit flies. In all the species in which it has been found to date, the homeo box appears to be a part of the blueprint for the regulation of development, but the nature of this regulation may vary from species to species.

Scientists view the homeo box and homeotic mutations as windows into understanding evolution as well as embryonic development. The similarity of homeo boxes between species shows the degree to which these species are evolutionarily related. Homeotic genes are also providing outstanding clues for understanding the developmental process--certainly one of the greatest mysteries in biology.

New Technique Helps Scientists Locate Genes on Chromosomes

One of the most important recent advances in genetics--the increased understanding of mutations caused by defects in homeotic genes--was largely due to a technique called chromosome walking. Before the development of chromosome walking, methods to determine the chromosomal location of a gene required a knowledge of the gene's products. Since the products of the two major groups of homeotic genes were not known, a new technique had to be developed to find the locations of these genes.

In developing such a technique, Dr. Hogness and his colleagues have given researchers invaluable information about the DNA of certain groups of genes. For example, isolation of the individual homeotic genes enabled scientists to use DNA from these regions as probes to look for similar sequences on other chromosomes. This resulted in the discovery of the homeo box.

Rather than being limited to more traditional genetic studies, which start with a known defective gene product (in this case a protein) and then work back to identify the gene responsible for that protein, scientists can now examine the DNA in the genes themselves and work the other way to find the gene product. Chromosome walking promises to save many years applications in genetics, and is already being used to look for particular genes of interest. These include many defective genes such as those causing Huntington's disease and Duchenne muscular dystrophy in humans.

New Hope for Curing Genetic Disorders

Despite the rapid advances in our knowledge of genetics and the development of methods to identify and study genetic disorders, there are still no cures for any genetic diseases. Medical support is currently limited to treatment of the symptoms of only a few of the most common disorders.

There is hope that this situation will improve in the future. Drugs made by recombinant DNA techniques are currently in use; a few genetic disorders can be detected and even treated prenatally; and our understanding of the genetic basis of many disorders is increasing. A number of researchers are now trying to utilize the concepts and technologies of modern genetics to find ways to cure genetic diseases.

A true cure for a genetic disorder would require that the defective gene be replaced with a normal one in some or all of the body's cells. It is currently very difficult, however, to insert a normal gene into the correct spot on a chromosome and have it be expressed in the proper amount at the proper time. If the inserted gene were to integrate inappropriately, it could disrupt normal genes or regulatory regions, and could result in health problems as serious as the original disorder.

Two NIGMS grantees have now made a major advance in gene replacement technology by successfully inserting a gene into a predetermined site on a human chromosome. Working with cells in test tubes, Drs. Oliver Smithies at the University of Wisconsin-Madison and Raju Kucherlapati at the University of Illinois at Chicago were able to insert into the correct chromosome the gene for beta-globin, a component of hemoglobin, the oxygen-carrying protein of red blood cells. This gene is the one that is defective in people who have sickle-cell anemia, as well as in some persons of Mediterranean ancestry who have a different type of anemia called thalassemia.

The new work reported by Drs. Smithies and Kucherlapati and their collaborators is still in its early stages and cannot yet be adapted to treatment. Nevertheless, it is very encouraging because until now no one has been able to make planned modifications, such as deletions or insertions, in specific genes of any organism more complicated than yeast. Their success raises the hope that modification of the defective beta-globin gene might someday be feasible as a treatment of--and perhaps ultimately a cure for--patients with disorders such as sickle-cell anemia and thalassemia. This research is clearly a step toward achieving that goal.

National Heart, Lung, and Blood Institute

Elevated blood cholesterol can be a consequence of metabolic disorders such as hypothyroidism or diabetes. It can also be caused by familial hypercholesterolemia (FH), a genetic disorder. Among FH heterozygotes (individuals who inherit a single copy of the defective gene), clinically significant coronary heart disease before age 60 is common. At least 1 in 500 Americans is an FH heterozygote. Homozygotes (people who have inherited flawed genes from both parents) are much less numerous (about 1 in 1,000,000), but may die from complications of atherosclerosis during childhood or adolescence.

FH is characterized by deficient or defective receptors that normally facilitate the uptake of low-density lipoproteins (LDL, the principal carriers of cholesterol in the blood) by cells. In cells with functional LDL receptors, the uptake and utilization of LDL cholesterol is efficient and body needs can be met at relatively low-level synthesis by the liver. But FH heterozygotes have about half the normal number of functional LDL receptors, and their livers respond by doubling the blood cholesterol level. In FH homozygotes, functional LDL receptors are fewer still and blood cholesterol levels are correspondingly higher.

It is often possible to normalize blood cholesterol in FH heterozygotes with a combination of diet and drug therapy. National Heart, Lung, and Blood Institute (NHLBI) intramural scientist Dr. Jeffrey Hoeg and his coworkers achieved normalization of blood cholesterol in 92 percent of FH heterozygote patients who complied fully with a regimen combining a cholesterol-lowering diet with the lipid (fat)-lowering agents neomycin (an antibiotic) and niacin (a vitamin). Although some patients discontinued niacin because of side effects, no significant side effects were observed with neomycin. This antibiotic may offer an attractive alternative to certain other cholesterol-lowering drugs, such as cholestyramine, that now have wider clinical use than neomycin.

Drs. Michael Brown and Joseph Goldstein, whose research in this area earned them a 1985 Nobel Prize, maintain that currently available measures for lowering blood cholesterol are effective only to the extent that they stimulate normal genes in the liver and other tissues to produce increased numbers of LDL receptors. Drs. Brown and Goldstein, NHLBI grantees at the University of Texas Health Science Center at Dallas, report that mevinolin, a new drug presently undergoing limited clinical evaluation in the United States, is showing special promise. A potent inhibitor of cholesterol synthesis in the liver, mevinolin forces the liver to rely more heavily on blood plasma cholesterol to meet its own needs. As a result, the liver must increase its production of LDL receptors. Since the liver contains up to 75 percent of all LDL receptors in the body, the resultant effect on blood cholesterol levels can be profound.

Neither mevinolin nor other conventional cholesterol-lowering measures offer much help for FH homozygotes, who lack the normal genes that might be prodded into generating increased numbers of LDL receptors. Still, there may be a solution--albeit a very limited one--for some of these victims: liver transplants. A case cited by the investigators involved an FH homozygote with no functional LDL receptors and an extremely high cholesterol level. By age 6 this patient had had a heart attack and had undergone two coronary bypass operations with no relief of her angina. The patient subsequently underwent a combined heart and liver transplant operation performed by Dr. Thomas Starzl and his coworkers, NHLBI grantees at the University of Pittsburgh Health Center. Afterward, her LDL cholesterol level fell by almost 80 percent, indicating that the receptors of the transplanted liver were removing plasma LDL cholesterol at a nearly normal rate.

In related work, Dr. Stanley Rall and his coworkers, NHLBI grantees at the University of California, San Francisco, have collaborated with scientists from England and from a U.S. corporation to determine the structure of the terminal third of the apolipoprotein B (apo-B) molecule and to identify those portions involved in its lipid- and receptor-binding functions. Apo-B is the constituent of LDL that appears to be the key to the uptake of plasma LDL cholesterol by cells of the liver and other tissues. The investigators consider their findings a step toward complete structural characterization of apo-B and the gene that directs its production. Such knowledge might provide new insights for favorably manipulating LDL levels and cholesterol metabolism in blood-lipid disorders.

Other laboratories are collaborating on research that could lead to human gene therapy. Drs. W. French Anderson and Arthur Nienhuis, NHLBI intramural scientists, have successfully transferred a functional ADA gene into the bone marrow of mice. In ADA deficiency, individuals lack adenosine deaminase, an enzyme crucial to normal development of the human immune system. The scientists determined that although the procedure works in mice, it is much less efficient when applied to monkeys. Before attempting to insert the gene into a human patient, considerable research must be done to improve the efficiency of this gene's insertion in monkeys.

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

Genetics research supported by the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) includes studies of the structure and production of hormones such as insulin, growth hormone, somatostatin (which stops the production of growth hormone), luteinizing hormone (which leads to release of an egg from the ovary), thyroid stimulating hormone, and parathyroid hormone. Other research focuses on the structure and function of genes controlling blood and connective tissue production; synthetic production of hormones and other substances important for the treatment of disease; prenatal diagnosis of certain blood and metabolic disorders; and means of determining populations at increased risk for developing diabetes, diseases of the joints, connective tissue disorders, and skin diseases.

McArdle's syndrome is an inherited disease that limits the ability of affected individuals to perform strenuous exercise due to painful muscle cramps. Because of a defective skeletal muscle enzyme, such exercise can result in acute kidney failure due to a sudden increase of muscle cell waste products in the blood and urine.

Dr. Robert Fletterick, an NIADDK-supported grantee at the University of California, San Francisco, has determined that the gene responsible for the defect in skeletal muscle enzyme is located on chromosome 11. Identifying the location of the defect could lead to the development of methods for early diagnosis and screening in family members of affected patients. Methods used in this project can now be applied to localize other disease genes.

Tay-Sachs disease causes progressive mental and motor deterioration in infancy that soon results in death. Most common among Ashkenazi Jews, it results from a genetically caused deficiency of a crucial enzyme. NIADDK intramural scientists Drs. Richard Proia and Rachel Myerowitz have studied the enzyme's normal biosynthetic pathway and the pathway's disruption, and have described several mechanisms for reduced enzyme production. They also cloned a gene that encodes part of the enzyme and that, when mutated, results in the disease. This work provides the basis for identification of the mutations that cause Tay-Sachs as well as insights into an important group of enzymes.

NIADDK grantee Dr. George Stamatoyannopoulos at the University of Washington in Seattle and his colleague Dr. Harold Weintraub at the Fred Hutchinson Cancer Research Center, also in Seattle, have developed a method of improved genetic analysis, called anti-sense transcription, that inhibits gene activity and thus allows the detection of otherwise hidden gene functions. By permitting researchers to selectively shut off a defective gene, this technique may one day be useful in gene replacement therapy. A normal replacement gene could then be introduced into the cells to provide the desired protein product.

National Institute of Neurological and Communicative Disorders and Stroke

Of the 2,000 known genetic disorders, as many as one-third significantly affect the nervous system, resulting in brain damage, brain tumors, and muscle wasting, among a range of disabling symptoms. A major goal of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) research program is to understand how the healthy nervous system works and what goes wrong when a defective gene is passed to a new generation. Much research emphasis is placed on identifying the specific gene responsible for a disease and finding ways to repair or replace it.

NINCDS research on the degenerative Huntington's disease and on Alzheimer's disease, which may have a genetic component, is described at length in separate reports.

Lipid Storage Diseases

Lipid storage diseases are life-threatening hereditary conditions involving an enzyme deficiency causing large quantities of [illegible] to accumulate in [illegible] tissues. NINCDS intramural scientists under the leadership of Dr. Roscoe Brady, have been working [illegible] with [illegible] the [illegible] of lipid storage [illegible] patients [illegible] enzyme deficiency. This year, Drs. John Barranger and Gary Murray developed a strategy for delivering an enzyme to the exact location in the [illegible] of the [illegible] Department of [illegible] University. Drs. Barranger and [illegible] have also completed work on a [illegible] to [illegible] enzyme [illegible].

Under Dr. Brady's direction, another NINCDS intramural research team comprising Drs. [illegible], [illegible], and Frank [illegible] has collaborated with scientists at the Massachusetts Institute of Technology in Boston to [illegible] important gains in understanding [illegible] level. After identifying and isolating the normal gene for the essential enzyme that [illegible], the investigators [illegible] gene into [illegible] cells [illegible] the enzyme deficiency. This [illegible] for Gaucher's disease [illegible].

Animal Models for Genetic Disorders

An [illegible] disease [illegible] inherited [illegible] research [illegible] at [illegible]

Tufts University School of Medicine in Boston reported this year that English springer spaniel puppies can inherit an enzyme deficiency that triggers neurological impairment, loss of motor coordination, and bone deformation--all symptoms of human infantile G_{M1}-gangliosidosis, a lipid storage disorder. The similarity between the human and canine diseases was largely confirmed when autopsies showed an excess of fatty material in the spaniels' brains. The scientists also found that the urine of the affected spaniels showed a sugar pattern similar to the pattern observed in the human disease. The Tufts team is now exploring the possibility of using this animal model to test such experimental treatments as enzyme replacement, bone marrow transplants, and gene insertion.

NINCDS intramural scientist Dr. George Constantopoulos and his colleagues at NIADDK and the University of Tennessee at Knoxville this year found another canine disease to be an excellent model for the human lipid storage disorder mucopolysaccharidosis I. Extensive biochemical analysis of affected canine tissue has shown that the disease resembles the lipid storage disorder in all respects. This model is an important advance in the design of experiments to improve treatment for mucopolysaccharidosis I and possibly find ways to prevent it.

Neurofibromatosis

At Massachusetts General Hospital in Boston, a research team led by NINCDS grantee Dr. Robert Martuza this year found that tamoxifen citrate, an antiestrogen compound, inhibits the growth of neurofibromatosis-related tumor cells in laboratory cultures and slows tumor cell proliferation in rats. These findings could form the basis for improved control over the tumor growth that is one of the most distressing characteristics of neurofibromatosis.

Neural Tube Defects

Spina bifida, or "split spine," is a birth defect in which protective tissue fails to close over the developing spinal cord, leaving the cord exposed. This condition, which can produce muscle paralysis, deformities, and bowel and bladder problems, is thought to have both genetic and environmental origins. Dr. Aubrey Milunsky at Boston University in Massachusetts this year began an NINCDS-funded study of 25,000 high-risk pregnancies to examine some of the suspected causes of spina bifida and other neural tube defects. The Boston team will correlate data from questionnaires and will analyze mothers' diets, levels of trace elements, and amniotic fluid. The scientists will also follow the health of children born of these pregnancies for 1 year after birth. Information derived from this long-term project could provide research leads for developing ways to prevent neural tube defects.

Tourette Syndrome

At Yale University in New Haven, Connecticut, NINCDS grantee Dr. David Pauls is investigating the role of genetic and environmental factors in neuropsychiatric disorders like Tourette syndrome. This year, Dr. Pauls has compared Tourette syndrome, symptoms of which include facial tics, involuntary muscle movement, and uncontrollable sounds, with obsessive-compulsive behavior, and has found evidence of similar inheritance patterns in both disorders. If the role of genetics in these diseases can be further clarified, scientists may be able to move beyond symptomatic treatment toward cure and prevention.

Neurogenetic Research Centers

This year NINCDS announced a special program of support for multidisciplinary research centers to study neurogenetic disorders of infancy and childhood. These disorders, which include neurofibromatosis, tuberous sclerosis, and Batten's disease, have been difficult to study because they are relatively rare and involve metabolic defects that are often unknown. The proposed multidisciplinary centers would provide both the scientific expertise and the new technologies needed to explore these puzzling disorders.

National Institute of Allergy and Infectious Diseases

Inherited defects in the function of immune system cells result in a wide range of immunodeficiency disorders. The National Institute of Allergy and Infectious Diseases (NIAID) is conducting and supporting research aimed at understanding the mechanisms involved in these defects, both to develop treatment for persons suffering from these inherited disorders and to learn more about the functioning of the normal immune system.

One type of genetic deficiency common among Western Europeans involves complement, a complex series of blood proteins essential for the normal immune response. Complement activity can kill bacteria, and it causes specialized cells to release chemicals involved in inflammation. Approximately 1 in 10,000 white persons has an inherited deficiency of a component of complement called C2. An estimated 50 percent of those with C2 deficiency suffer from autoimmune diseases such as systemic lupus erythematosus, and they may also have an increased susceptibility to bacterial infection and chronic kidney disease.

NIAID-supported researchers are investigating the molecular basis for C2 deficiency. Dr. Harvey Colten at Children's Hospital in Boston and his colleagues found that this deficiency results from a regulatory error involving messenger RNA (molecules that direct the synthesis of specific proteins) rather than a major gene deletion or gross rearrangement. C2 messenger RNA was not detectable in the cells of C2-deficient patients, which explains their inability to synthesize the C2 protein. The approach used in this study has proven to be of value in identifying the cause of other plasma protein deficiencies as well, such as alpha1-antitrypsin deficiency, and C3 and C4 deficiencies in animal models.

Another genetic disorder involving a deficiency affecting the immune system is called severe combined immunodeficiency disease (SCID). One form of SCID is ADA deficiency. Unlike the well-known "bubble boy," David, who lived his life in a sterile environment, most children with SCID die early in childhood unless they receive a bone marrow transplant that provides them with functional immune system cells. This treatment is subject to failure, however, because in most cases no bone-marrow donor can be found with compatible tissues. Tissue compatibility is necessary to prevent graft-versus-host disease, an often-fatal complication of such transplants.

A potential treatment for SCID and other genetic disorders is gene replacement therapy. ADA deficiency is a promising candidate for this new technique, and research is advancing toward that goal. NIAID grantee Dr. Rodney Kellems at Baylor College of Medicine in Houston used genetic selection techniques to develop a mouse cell line (a group of continuously reproducing cells grown in test tubes) containing over 10,000 times the normal amount of

ADA enzyme, the highest level of enzyme production ever achieved by this method. When extracted from the cells and purified, the enzyme can provide sufficient quantities of ADA for further studies of enzyme replacement therapy. The cell line also facilitated isolation of the normal ADA gene from mouse cells. Dr. Kellems inserted the mouse ADA gene into ADA-deficient bacteria, which were then able to produce the enzyme.

In order to put the gene in mammalian cells, a vector (carrier) must be used. Dr. Kellems and other researchers working in this field have placed the gene into a retrovirus (a type of virus that can be made noninfectious but is still capable of inserting its contents into a cell's genetic material) that was then inserted into mammalian cells. The cells incorporated the gene and produced a high level of functional enzyme.

Inherited immune disorders involving phagocytic cells are rare in the United States, but their study is helping medical researchers better understand the complex workings of the immune system. Phagocytes are white blood cells that are important in fighting disease. They migrate to sites of inflammation and engulf and kill bacteria. People with defects of phagocytic function develop a wide range of recurrent life-threatening infections as well as other symptoms. A number of these disorders are under study by NIAID investigators.

One type of phagocyte that is critical in host defense against invading bacteria is the neutrophil, the most numerous type of white blood cell. The role of the neutrophil in oral health was recently studied by NIAID intramural scientist Dr. John Gallin and his colleagues at the National Institute of Dental Research, Drs. Stephan Mergenhagen and Jacques Charon.

They examined the mouths of 27 persons with defective neutrophil function. Compared to a control group, young people with neutrophil disorders frequently had ulcers in their mouths, and their gums and tissues supporting the teeth were inflamed even when antibiotics were taken. Two patients had had all of their teeth extracted before age 15 because of severe periodontal disease. These findings suggest that normal neutrophil function is an essential protective mechanism against oral disease.

Dr. Gallin studied another genetic disorder of phagocytes to understand the underlying basis for a constellation of symptoms that includes difficulty with wound healing, recurrent infections, and severe periodontal disease. These patients were reported to have abnormalities in phagocytic function, but the specific defect had not been defined. Dr. Gallin found that the phagocytes in patients with this disorder lacked a certain cell receptor. The absence of this receptor was associated with abnormal chemotaxis (movement of phagocytes to the site of invading organisms), abnormal bone marrow cell adherence, and abnormal aggregation of cells.

National Institute of Child Health and Human Development

More than a quarter of a million American infants are born each year with mental and physical defects, the leading cause of death for babies less than 1 year of age. The National Institute of Child Health and Human Development (NICHD) conducts research on prenatal development as well as clinical studies of people with genetic diseases.

NICHD has established a repository in Rockville, Maryland, that will be a central warehouse where copies of human DNA segments, called DNA probes, can be collected, stored, and distributed to scientists nationwide. By using a computerized "catalogue," researchers can obtain information about and purchase human DNA sequences for research or diagnostic purposes.

DNA probes have become valuable tools for genetic researchers to use in locating genes on specific chromosomes, reproducing numerous copies of genes, and distinguishing normal genes from abnormal ones. Using DNA probes, scientists can determine before birth if an infant will inherit certain genetic diseases, such as the blood disorder thalassemia.

Another area of research involves sex chromosome abnormalities. One study being conducted by Dr. Larry Shapiro, an NICHD grantee at the Los Angeles Center for Health Services in Torrance, California, concerns the genetics and biochemistry of the steroid sulfatase system, which plays a major role in the synthesis of hormones and regulates other aspects of metabolism in later life. About 1 in 6,000 males is born genetically deficient in steroid sulfatase. They are usually born to women who have deficient estrogen production during pregnancy. Affected newborns develop a common skin condition, ichthyosis, in which cholesterol sulfate accumulates in skin. The location of the steroid sulfatase gene on the human X chromosome (one of the two types of sex chromosomes) is now known. In an additional study, the gene will be cloned to examine it in greater detail and learn how a defect in the gene can cause disease.

In the area of developmental genetics, NICHD grantee Dr. Davor Solter of the Wistar Institute of Anatomy and Biology in Philadelphia is using a mouse model system to determine differences between maternal and paternal chromosomes. Diploid (paired) chromosomes are necessary for embryo development. In one experiment, one chromosome was substituted for another in the pair after fertilization had occurred. This procedure did not disrupt development as long as the maternal-paternal balance was maintained. However, when the result of the substitution was two paternal chromosomes or two maternal chromosomes, development did not proceed normally even though the diploid requirement was still met. This result suggests that maternal and paternal chromosomes are programmed differently.

National Eye Institute

Four hundred thousand Americans are visually impaired because of hereditary or congenital disease, and these disorders are responsible for one out of every five cases of blindness in the United States. The economic impact of these genetic disorders is heightened by the fact that the visual impairment they cause generally begins early in life and continues through the middle years, when economic productivity would ordinarily be at its highest. Thus, they are believed to account for a significant portion of the $16 billion that Americans spend each year for treatment and special services necessitated by visual disorders and disabilities. The National Eye Institute (NEI) supports research to find new ways of diagnosing, treating, and eventually preventing these disorders.

Retinitis pigmentosa (RP) is the general name for a group of genetic eye diseases that receive particular emphasis in the NEI research program. These blinding disorders typically strike in childhood or adolescence and gradually destroy the retina, the light-sensing tissue at the back of the eye. They are estimated to affect 100,000 Americans, and at present there is no treatment for them.

For years, scientists have been hampered in their efforts to find effective treatments for the various forms of RP because the specific genetic and biochemical defects responsible for retinal breakdown in these disorders are difficult to identify. Now, NEI-supported scientists are participating in a major international effort to overcome this problem through the new techniques of molecular genetics. The key molecular tools that the scientists are employing are DNA probes. NEI grantees were the first scientists to use these molecular genetic techniques successfully in patients with hereditary eye disease.

Now, laboratories around the world are applying this new technology to search for the genes that give rise to hereditary retinal degenerations. In the past year, probe technology has allowed scientists to come very close to locating the genes responsible for two of these disorders- choroideremia and the X-linked (its gene is located on the X chromosome) form of RP. For each of these genes, the range of possible locations has been narrowed to a tiny segment of one chromosome. In each instance the scientists were able to use clues provided by the probes to tell which members of a large extended family had the gene for the hereditary disease. These probes may someday be used in genetic counseling of some families at risk for these hereditary diseases. Even more exciting, the genes responsible for these diseases may eventually be isolated and studied in the laboratory, perhaps giving scientists the opportunity to learn enough about the biochemical basis of the disorders to devise effective therapies.

NEI grantees Drs. Eliot Berson and Thaddeus Dryja at Harvard Medical School in Boston are contributing to recent advances in the localization of genes involved in hereditary retinal degenerations. They have confirmed and refined other investigators' estimates of the location of the gene for X-linked RP, and are now beginning to broaden the scope of this work to include the difficult-to-locate genes that are responsible for the more common, autosomal (non-sex-linked) forms of RP.

Molecular biological techniques are also being used with great success in NEI's basic retinal studies, the findings of which are expected to be highly relevant to the problem of RP. In the past year there was a major breakthrough in the laboratory of NEI scientist Dr. Gerald Chader. He and intramural investigators Drs. John Nickerson and Barbara Wiggert succeeded in isolating and cloning from bovine tissue the gene that codes for a little-understood protein that helps regulate the movement of nutrients such as vitamin A to and from the light-sensing cells of the retina. Other recent work by Dr. Chader's group has suggested that the disappearance of this protein may be one of the earliest changes detectable in some eyes with RP. Thus there is hope that further study of the protein and the gene that codes for it may yield valuable insights into mechanisms underlying this group of diseases.

Even more rapid progress is occurring in the study of gyrate atrophy, another blinding disorder that is related to RP. Gyrate atrophy is perhaps the best defined of the hereditary retinal degenerations because research by NEI scientist Dr. Muriel Kaiser and NEI grantee Dr. David Valle at The Johns Hopkins University in Baltimore has revealed that patients with the disease have a genetically determined deficiency of an enzyme called OAT. Within the past year, NEI scientist Dr. George Inana and his coworkers have isolated and cloned the gene for this enzyme. They are now engaged in an intensive study of the OAT gene with the hope of identifying the abnormalities that are responsible for gyrate atrophy. A long-term goal of this work is to develop a gene therapy for the disease.

In addition to these promising studies on hereditary retinal degenerations, NEI supports research on many other visual anomalies that have a genetic component. These include retinoblastoma, hereditary cataract, strabismus (misalignment of the eyes), and color deficiency. NEI-supported studies continue to yield findings that will improve the understanding, diagnosis, and treatment of hereditary eye disorders, thus furthering progress toward the prevention of visual impairment.

National Institute on Aging

Aging is the result of a complex interaction between many simultaneous processes. Aging may be genetically programmed and environmental factors may alter either the expression of this program or the functions of the gene products. This assumption is based on the observation that lifespan tends to be fairly constant among members of a given species, whereas there are vast differences between species.

The major thrust of the National Institute on Aging's (NIA) extramural research in genetics is the elucidation of the nature of the genetic program determining lifespan. To accomplish this goal, NIA supports research in a variety of areas: DNA structure, synthesis, and metabolism; gene expression and its control; genetic theories of aging; and cell growth, differentiation, and reproduction.

Normal cells grown in culture have a finite lifespan, usually being able to divide about 50 times. Assuming that this reflects some process involved in normal aging, NIA grantee Dr. Eugenia Wang at The Rockefeller University in New York City has obtained evidence of the existence of a protein (called statin) in aging cells that is absent in young cells. Now she is working to isolate and characterize the protein to determine how it functions in the aging process.

From cell fusion studies, Dr. James Smith at Baylor University Medical School has also obtained evidence of a senescence protein that blocks DNA replication. Dr. Smith, an NIA grantee, postulates that this protein may be responsible for the inability of senescent cells to divide. Because cell division is basic to the life of the cell, this theory may have great significance to aging.

NIA grantee Dr. Arthur Kornberg at Stanford University is pursuing a different, but related, approach. Cell division cannot take place until DNA replication has occurred, and the first step in DNA replication is initiation. Dr. Kornberg has elucidated many of the details of initiation in bacterial cells, and it is hoped this will provide a solid basis for studying DNA replication in mammalian cells.

A longstanding assumption is that damage to DNA hastens senescence through a variety of mechanisms. If true, lifespan should be a function of DNA repair capacity. Preliminary results from investigators support this assumption. NIA grantee Dr. Philip Hanawalt at Stanford University has found that the ability to repair DNA in mammalian cells depends on the type of damage, its location on the chromosome, and the functional state of the DNA. Dr. Hanawalt's objectives are to relate these findings to developmental and aging changes.

The NIA's intramural Laboratory of Neurosciences (LNS) supports several projects in which genetics is a key element. The LNS is studying the cerebral metabolism of subjects with Down syndrome or other developmental abnormalities that are genetically determined. Subjects with a familial form of Alzheimer disease are also being studied as a part of the search for genetic markers for this disease.

Genetic disorders related to aging can be divided into at least two categories: progeroid syndromes (present the aging diseases) that could be models for normal aging, and genetic defects that are expressed late in life. Individuals with progeria have a very short life expectancy and usually die from heart failure before the age of 20. Patients suffering from these syndromes are very helpful for studying diseases that are more frequent in older life (diabetes, cardiovascular disease, arthritis, and osteoporosis). Werner's syndrome is a related disease that starts in adulthood rather than in childhood.

Dr. [illegible], of the Fels Institute of Temple University in Philadelphia, is studying the growth of cells derived from progeroid patients. This research has yielded information about the importance of growth factors in progeroid cells, a finding that could prove important for research on the process of aging.

Division of Research Resources

For children born with a rare and incurable skin disease, even slight friction causes their fragile skin and mucous membranes to blister, subjecting them to frequent scarring and the almost constant threat of secondary infection.

All but one of the approximately 20 types of this incurable disorder, called epidermolysis bullosa (EB), are hereditary. And even the mildest and most common form--a nonscarring disease called localized EB simplex--can transform walking, typing, and other routine activities into painful ordeals. Many children with this disease die before age 30. The Dystrophic Epidermolysis Bullosa Research Association of America estimates that between 25,000 and 50,000 Americans have one of the forms of EB.

Each year scientists conduct thousands of research studies in the 78 General Clinical Research Centers (GCRC's) supported by the Division of Research Resources (DRR). More than 80 percent of the extramural inpatient research care funded by the National Institutes of Health takes place in GCRC's, which are located at major medical centers in the United States. In addition, GCRC scientists carry out extensive outpatient research.

Clinical trials are now under way at several GCRC's to evaluate phenytoin, an anticonvulsant drug that may be effective in reducing blistering in patients with recessive dystrophic EB. The trials, which are being co-funded by DRR and the Office of Orphan Products Development of the Food and Drug Administration, evolved from DRR-supported preliminary studies performed by Dr. Eugene Bauer and his colleagues at the Washington University GCRC in St. Louis.

In 14 of 22 patients with recessive dystrophic EB treated with phenytoin, the number of blisters and skin erosions decreased by an average of 46 percent. When the drug was discontinued, blistering returned to pretreatment levels.

Dr. Bauer and his colleagues also are evaluating the therapeutic value of vitamin A derivatives, called retinoids. The Washington University researchers found that 13-*cis*-retinoic acid significantly reduced the number of blisters in the three patients studied. However, the compound caused drying of the skin, headaches, and other serious side effects, even at low dosages. According to the researchers, the findings suggest that the retinoids are promising therapeutic agents but that additional study is needed, particularly to establish dosage levels that minimize the potential for side effects.

Other DRR-supported research has led to the development of a computerized system for diagnosing genetic diseases. According to DRR grantee Dr. Charles Sweeley at Michigan State University (MSU) in East Lansing, the computer can identify more than 40 genetic disorders. The system is located at the MSU Mass Spectrometry Facility, one of 61 research centers supported by DRR's Biomedical Research Technology Program. Research at these centers is focused on the application of the physical sciences, mathematics, and engineering to biology and medicine. The centers are divided into three main categories: resources in biomedical computing, biomedical engineering, and biomolecular and cellular structure and function.

Research using new, laser-activated cell sorters that can analyze individual cells at a rate of up to 5,000 per second and then create uniform samples of desired cells may also lead to significant progress in the study of genetic diseases. These machines allow scientists to determine not only the DNA content of a cell, but also the distribution and textural arrangement of the spiral DNA filaments within its nucleus.

The cell sorter allows researchers to gather pure samples of cellular components. Several teams of scientists have used the cell sorter in the Laboratory for Cell Analysis at the University of California, San Francisco, to prepare samples of individual chromosomes and to identify abnormal chromosomes.

This instrument was purchased with funds from DRR's Shared Instrumentation Grant (SIG) Program. The SIG Program provides sophisticated research instruments to be shared among Public Health Service-supported investigators. It is part of DRR's Biomedical Research Support Program, which supports more than 9,000 pilot and regular health-related research projects, including 810 focused on genetic diseases, at [illegible] institutions in the United States. The SIG Program was initiated by DRR in 1982 to help the biomedical research community cope with rapid technological advances in instrumentation and the rapid rate of obsolescence of existing equipment.

HEALTH RESOURCES AND SERVICES ADMINISTRATION
Bureau of Health Care Delivery and Assistance

GENETIC DISEASES

Title XI of the Public Health Service (PHS) Act formerly provided authority for the establishment of a national program to provide for basic and applied research, training, testing, counseling and information and education programs with respect to genetic diseases, including sickle cell anemia, Cooley's anemia, Tay-Sachs disease, cystic fibrosis, dyautonomia, hemophilia, retinitis pigmentosa, Huntington's chorea and muscular dystrophy.

The Title XI authority was superseded by the Omnibus Budget Reconciliation Act of 1981, which modified Title V of the Social Security Act to provide for a Maternal and Child Health Service Block Grant, and included the Genetics Program as part of a 15% set-aside for discretionary Consolidated Federal Programs.

Genetic diseases are a significant health problem. In the United States, one child in every 150 to 200 live births or a total of 15,000 to 20,000 infants each year has a major genetic anomaly. A study in Baltimore indicated that nearly one-third of hospitalized children had diseases that were "gene-influenced."

Currently 97 percent of newborn infants are receiving genetic screening, primarily for phenylketonuria (PKU). This metabolic disorder which accounts for less than one percent of all genetic diseases causes severe mental retardation if untreated. In most instances of PKU and a few other genetic disorders, prompt diagnosis and treatment will prevent adverse effects. The reduction of genetic diseases is primarily dependent on early identification of carriers of genetic disease traits through screening, testing and appropriate genetic counseling. Amniocentesis is a procedure used to detect or rule out some genetic conditions in the unborn fetus. Provision of genetic counseling based on results of prenatal testing permits individuals to make an informed decision regarding the risks of having a child and/or prepares them for the care of an affected child.

Except for EKU and sickle cell disease screening, genetic screening and diagnostic and counseling services are generally less available to some segments of the population, especially those groups at high risk which are served by the Department of Health and Human Services (HHS) programs. Laboratory resources required for genetic testing are extremely limited. Since the inception of the Federal Genetics program, there has been a significant increase in the availability and linkage of genetic testing and counseling services to the rest of the health care delivery system.

Information on the incidence and prevelance of genetic diseases varies considerably. For example, fairly well established figures are available for sickle cell anemia, cystic fibrosis and Tay-Sachs disease, while almost no reliable figure is available for retinitis pigmentosa; figures for diseases such as Huntington's chorea and muscular dystropy vary widely. Similarly, the state of technological development in screening and testing also differs considerably for those diseases. Identfication of carriers of sickle cell anemia, Cooley's anemia and Tay-Sachs is possible through available screening tests, whereas identification of carries for cystic fibrosis is still under study, and reports of available screening tests for carriers of hemophilia are sometimes not conclusive. The course of illness and prognosis also varies from Tay-Sachs disease, which is fatal in the first few years of life, to Huntington's chorea, which generally becomes manifest only in the fourth decade of life, although earlier onset is known to have occurred.

The major Genetic Diseases programs in existence through Fiscal Year (FY) 1985 were the following:

Grant Programs for the Development and Operation of Statewide Genetic Diseases Systems - Sixteen projects continued development and implementation of Statewide or regional systems of genetic care. All projects coordinated their activities with existing health care delivery systems and especially with the Maternal and Child Health programs supported under Title V of the Social Security Act.

Sickle Cell - Two awards were made for multi-State programs for the education, screening and counseling of couples at risk for having an infant with Sickle Cell Disease or other hemoglobinopathy. These projects stress cooperation between Sickle Cell clinics and heretofore unrelated tertiary Sickle Cell centers.

Genetic Networks - Awards were made to four States for the development and implementation of coordinated multi-State genetic services networks for defined geographic areas in order to provide better quality of care to the target population by sharing expertise and resources and providing more efficient means of access and service delivery.

Information and Education Services - The expansion of the National Clearinghouse for Human Genetic Diseases into the National Center for Education in Maternal and Child Health has resulted in a much broader-based resource with improved access and dissemination of information related to all areas of Maternal and Child Health to State and local programs, private agencies and the public.

Interagency Agreements - Interagency agreements supported unique contributions from other HHS constituent agencies, such as the Center for Disease Control, for laboratory quality control through proficiency testing and standardization for PKU and congenital hypothroidism.

The BHCDA programs also encouraged and assisted other PHS facilities such as, Indian Health Service and other Federal programs, to participate actively in the areawide genetic service networks.

The Genetic Diseases activities of the BHCDA have been incorporated into the 15% set-aside portion of the Maternal and Child Health Block Grant appropriation since FY 1982.

HUNTINGTON'S DISEASE

Obligations

	1983	1984	1985	1986 Appropri-ation	1986 Available After Se-questering	1986 Revised Estimate	1987 Estimate
Public Health Service:							
National Institutes of Health:							
National Institute of Neurological and Communicative Disorders and Stroke.............	13,094,000	14,619,000	17,357,000	18,986,000	18,170,000	17,751,000	17,563,000
Total, NIH..........	13,094,000	14,619,000	17,357,000	18,986,000	18,170,000	17,751,000	17,563,000

NATIONAL INSTITUTES OF HEALTH
National Institute of Neurological and Communicative Disorders and Stroke
HUNTINGTON'S DISEASE

Building on the dramatic discovery in FY 1984 of a marker for Huntington's disease (HD), many investigators focused this year on analyzing tissues of HD families to verify the marker's accuracy. If the marker's validity holds, soon it may be possible to test persons at risk for HD before they exhibit symptoms and predict, with confidence, who will ultimately develop the disease and who will not.

HD is a dominant genetic disorder passed on by an affected parent to his or her children, each of whom has a 50 percent chance of inheriting the defective gene and developing the disease. The malady affects about 25,000 people in the United States, and 100,000 more are at risk.

HD is caused by the premature death of nerve cells in a number of areas in the brain, particularly in the basal ganglia, a region involved in coordinating movement. Most victims first exhibit symptoms when they are between 35 and 45 years old, although some are under 20 or over 60 when the disease strikes. Symptoms vary, but they often begin unobtrusively in the form of restlessness, irritability, depression, and other emotional disturbances similar to those experienced by many people. There are also subtle involuntary movements, such as stumbling, slight facial tics and occasional slurring of speech, that may lead those at risk for HD to suspect they have the disease even if they do not. Early diagnosis may be difficult.

Because HD is a devastating, progressive disease, with symptoms that include disabling writhing movements and intellectual and emotional impairments, the patient eventually is confined to a wheelchair or bed and is unable to communicate. Death usually occurs 10 to 20 years after the first symptoms appear, and is often caused by other factors indirectly related to the disease, such as head trauma, infections or choking.

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) serves as the Federal Government's focal point for HD research. The discovery of the marker by NINCDS grantees led by Dr. James Gusella at Massachusetts General Hospital in Boston represented an essential step towards the Institute's goal of isolating the HD gene, defining the basic defect, and eventually devising therapeutic or preventive measures. But the marker could also signal difficult decisions ahead for HD families now that there is the possibility of a diagnostic test.

The Test for HD

The marker that is associated with the HD gene, arbitrarily called G8, was found on chromosome 4. For a test to be reliable, scientists must confirm that this location applies to all HD families. So far, 15 extended families have been analyzed, and all carry the marker on chromosome 4. NINCDS grantee Dr. James Gusella and his colleagues at Massachusetts General Hospital plan to confirm this location in 25 families before they use this marker to test people at risk.

At The Johns Hopkins University in Baltimore, Maryland, NINCDS grantee Dr. Susan Folstein has studied two ethnically different families and this year reported evidence of G8's validity despite differing clinical symptoms and racial diversity. Members of both families had G8 on chromosome 4. In the family of American blacks, however, Dr. Folstein found that members exhibit HD symptoms relatively early in life and show rigidity and absence of movement, but rarely have severe depression. In the family of German descent, members develop HD later and rarely exhibit rigidity or absence of movement, but are often severely depressed.

The test for HD so far has been about 95 percent accurate. Genetic recombinations that move the marker from one chromosome to its complementary chromosome seem to occur 5 percent of the time and result in a false test outcome. Identification of a second marker on the other side of the gene, a so-called "flanking" marker, would make the test 99.8 percent accurate, because recombination of both markers would be extremely rare. The flanking marker would also hasten progress in locating the gene itself.

Dr. Gusella and his research team made important progress this year in locating a second marker. They studied people with a rare condition called Wolf Hirschhorn disease, in which individuals lack the top of the short arm of chromosome 4. Dr. Gusella's team found these patients are also missing the marker G8, indicating that the HD gene is located close to the tip of chromosome 4's short arm. The team has focused its attention on this small area and has developed new genetic probes for use in the exploration.

HD Families: An Important Research Resource

In their search for the defective gene and other abnormalities peculiar to HD, investigators are collecting, studying, and sharing physical and psychological information provided by HD families.

The two NINCDS-supported Huntington's Disease Centers Without Walls increased their HD family populations this year. The Center in Boston, headed by Dr. Joseph Martin of Massachusetts General Hospital, is following 240 extended families. Scientists there have now identified 230 family members who have HD and 1,800 who are at risk. The Center in Baltimore, headed by Dr. Marshal Folstein of The Johns Hopkins University, maintains records on 475 extended families and has identified 300 family members with HD and about 850 more who are at risk.

Families outside the United States are also important to the HD research program. This year NINCDS grantee Dr. Nancy Wexler of the Hereditary Disease Foundation in Santa Monica, California, journeyed for the fifth time to Lake Maracaibo, Venezuela, to collect blood and tissue samples from a population of 3,000 members of an extended family with a very high rate of HD. The Venezuela family represents the largest living concentration of the disease anywhere in the world; the incidence of the disorder there is about 100 times greater than anywhere else.

The NINCDS-supported Research Roster for Huntington's Disease Patients and Families at Indiana University in Indianapolis, headed by Dr. Michael Conneally, this year increased to 5,000 the number of participants willing to provide information for research. Analyses of roster data are adding to the growing body of scientific knowledge about HD.

Based on information from the roster, Dr. Lindsay Farrer and colleagues at Indiana University this year reported that diabetes is significantly more prevalent in HD patients, which suggests that physicians should monitor these patients' glucose levels periodically. In another study led by Dr. Farrer, roster data suggested the presence of a maternally derived protective factor, because persons with early onset of HD predominantly have inherited the gene from the father, while late onset often means they have inherited it from the mother. The study also provided preliminary statistical data supporting the hypothesis that age at onset of HD and age at death may be influenced by "aging genes" that may determine longevity. If HD patients have these hypothesized genes that speed up the aging process, they may still be protected by the hypothesized maternal factor, the investigators suggest.

Other Approaches to HD

Other studies of HD focus on the disease's symptoms as a means of detecting the disease early and predicting the degree of impairment.

Dr. James Brandt, an NINCDS grantee at The Johns Hopkins University, this year reported on neuropsychological predictors of HD using the Wechsler Adult Intelligence Scale (WAIS). He found that length of illness is a poor predictor of the severity of dementia, because the onset of HD is difficult to establish with certainty. Severity of motor impairment was a more highly predictive measure in assessing an HD patient's thought processes. In a second study, Dr. Brandt tested an earlier finding that persons at risk for HD showed greater variability than normal on certain WAIS scores. He found this not to be the case.

Taking another approach, NINCDS grantee Dr. David Zee, also of The Johns Hopkins University, has been studying subtle eye movement abnormalities in mildly affected HD patients. He reported this year on a series of tests that showed that these patients cannot perform such tasks as looking in the opposite direction from an object when asked to do so. His findings might have implications for early identification of persons with HD. Dr. Zee intends to study correlations of his findings with two brain imaging techniques--positron emission tomography (PET) and computed tomography (CT)--as well as neuropsychological testing.

Dr. Anne Young, an NINCDS grantee at the University of Michigan Hospital in Ann Arbor, has found that the PET scan provides a sensitive index of the decline in HD patients, because it shows the extent of damage to the brain, which has been found to correlate with the severity of clinical symptoms. She is using PET to study patients in the early and middle stages of the disease, as well as those at risk. This year she analyzed data from 20 of her 40 presymptomatic patients and found that half have a slightly abnormal PET scan. Based on these limited findings, PET appears to be able to provide new information on the earlier stages of HD.

Probing the HD Brain

How the HD gene produces the disease is still a mystery. Scientists hope to identify the chemical and structural abnormalities in the brain caused by the gene.

Dr. Joseph Martin of Massachusetts General Hospital has been investigating the cells in the striatum, the brain region most severely affected by HD. Three types of cells--large, spiny, and aspiny--have been identified in this area. This year Dr. Martin found that aspiny cells, which are scattered throughout the striatum, survive in the brain of HD patients, whereas the other types of cells die. These aspiny cells are the only ones to contain certain chemicals (somatostatin, neuropeptide Y, and NADPH-d) that may provide a clue to their selective survival in an area of the brain where massive death of other nerve cells occurs.

Dr. Henry Wagner, Jr., an NINCDS grantee at The Johns Hopkins University, is studying the receptors for dopamine in the basal ganglia in 16 HD patients, using PET technology. Dopamine is a natural brain chemical involved in the initiation and control of movements. This year Dr. Wagner found that the number of dopamine receptors is reduced in these patients. Receptor decline appeared to be a function of cell death, rather than a defect in the receptors themselves. Dr. Wagner has identified four other receptors for future study.

The role of neurotransmitters in the death of certain brain cells is being studied by Dr. Joseph Coyle, another NINCDS grantee at The Johns Hopkins University. Using selected drugs, such as kainate, he has tested the response of certain nerve cell receptors--called excitatory glutamate receptors--in rats and in post mortem brain tissue from HD patients. In both tissues, the response ultimately results in cell death. This year Dr. Coyle identified a naturally occurring substance in rat brains that may act as an excitatory neurotransmitter and cause nerve cell destruction. This substance interacts with rat glutamate receptors. He is now measuring the substance in brain tissue from HD patients, while studying its role in the normal exchange of nervous impulses across synapses.

Research Outlook

Given the pace of current research, identification of a flanking marker for the HD gene and availability of a test for HD prenatally and in asymptomatic, at risk individuals, are distinct possibilities for the near future. Along with this progress will come certain problems currently being discussed in the research community and among voluntary organizations. Attention is being given to the impact of administering the HD test to individuals at risk for the disease without being able to offer a cure or effective treatment. All acknowledge the need to find ways to help patients cope with unfavorable test results so that they can make plans for the future. Isolating the HD gene itself remains an exciting challenge for neuroscientists. But the larger goal is to determine and correct the gene's fatal flaw, a process with important implications for many genetically determined diseases.

HYPERTENSION

Obligations

	1983	1984	1985	1986 Appropriation	1986 Available After Sequestering	1986 Revised Estimate	1987 Estimate
Public Health Service:							
National Institutes of Health:							
National Heart, Lung, and Blood Institute.	85,769,000	93,944,000	97,047,000	103,800,000	96,952,000	95,552,000	88,202,000
National Institute of Child Health and Human Development...	1,290,000	1,875,000	2,176,000	2,300,000	2,200,000	2,200,000	2,200,000
National Institute on Aging............	1,949,000	1,739,000	4,862,000	5,018,000	4,964,000	4,957,000	4,922,000
Division of Research Resources	6,481,000	5,465,000	6,137,000	6,279,000	6,009,000	6,009,000	5,657,000
Total, PHS...........	95,489,000	103,023,000	110,222,000	117,397,000	110,125,000	108,718,000	100,981,000

National Institutes of Health

National Heart, Lung, and Blood Institute

HYPERTENSION

Hypertension, or high blood pressure, is a major health problem in the United States. According to the 1985 report of the Subcommittee on Definition and Prevalence (a subcommittee of the National Heart, Lung, and Blood Institute's (NHLBI) Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure, or JNC), approximately 58 million Americans have high blood pressure. This figure does not include persons with high blood pressure who are controlling it with dietary modifications, weight loss or other nonpharmacologic means.

Hypertension is defined as a blood pressure of 140/90 mmHg or above. The number 140 is the systolic blood pressure, which is the pressure exerted against the walls of the arteries when the heart beats. The bottom figure, 90, is the diastolic blood pressure, which is the pressure that remains in the arteries between heart beats. The numbers are reported in millimeters of mercury or mmHg, a unit of measure of pressure.

The 1980 JNC report had defined hypertension as a blood pressure of 160/95 mmHg, which "increased" the number of people who have high blood pressure of 160/95 mmHg, or above. The 1985 report lowered the defined limit of hypertension to 140/90 mmHg, which "increased" the number of people who have high blood pressure while at the same time "reducing" the number of those who are aware they have it.

The change in definition of hypertension also affects the percentage of people who are being treated for the disease. From 55.6 percent who were being treated under the 1980 definition of the disease, the percentage being treated under the new definition dropped to 33.1 percent of the hypertensive population. At the 140/90 mmHg level, the percentage of women on treatment (44.1 percent) is nearly double that of men (23.3 percent) being treated. A slightly higher percentage of blacks than whites are being treated for high blood pressure.

At the 140/90 mmHg level, the percent of hypertensives whose high blood pressure is under control increases with age until age 54 and then seems to level off. Control rates range from as low as 2.2 percent for 18- to 24-year olds to 14 percent for the 55- to 64-year olds. The control rate for women is much higher than that for men (16.7 percent versus 6.1 percent, respectively). Black women have the best rate of control, 19.2 percent. Redefining the lower limit of high blood pressure has also had a "detrimental" effect on overall control rates. Under the previous definition of hypertension as 160/95 mmHg, 34.2 percent of hypertensives were controlling their disease. With the newly defined level of hypertension, the control rate for all hypertensives drops to only 11.1 percent. This may be partially explained by the fact that physicians may not yet be initiating treatment for hypertension at the lower level.

In general, the prevalence data show that men tend to have a higher frequency of hypertension than women until about age 55 when both sexes' rates become similiar. After age 64, the prevalence of hypertension among women surpasses that of men. This in part reflects the greater prevalence of a condition called isolated systolic hypertension, or ISH, (systolic pressure 160 mmHg or higher, with the diastolic pressure below 90 mmHg) among women aged 64 and older. More than 3 million Americans over the age of 60 have ISH and the condition promises to become more prevalent over the next decade as the number of elderly people is expected to increase by 20 percent.

To study the risks and benefits of treating ISH, the NHLBI in conjunction with the National Institute on Aging is conducting a major clinical trial to determine if deaths from stroke, cardiovascular disease and other consequences of hypertension are reduced in elderly patients who receive drug treatment for ISH. Another question to be answered is what effect the treatment has on the quality of life of the patients. A full discussion of the progress in this long-term trial is included in the separate report on aging.

According to the JNC report, slightly more than half of all hypertensives are aware that they have high blood pressure. Awareness ranges from 24 percent of the population aged 18 to 24 to 62.9 percent among persons ages 65 to 74. More women than men are aware of their high blood pressure.

In addition to the JNC's recent revision of high blood pressure prevalence data, the National High Blood Pressure Education Program Coordinating Committee--sponsored by NHLBI--has also issued a revised statement on devices used for the measurement of blood pressure. Several factors led to this revision. New information about the use and accuracy of blood pressure measuring devices has become available; sales of such devices have increased; and health professionals have become increasingly interested in the use of ambulatory blood pressure measuring devices, which has led to questions about the appropriateness of such devices for control of high blood pressure.

The revised statement addressed three types of devices: those portable devices used at home, stationary automated machines (some of which are coin-operated devices found in commercial outlets, shopping malls and so forth), and ambulatory monitors that take blood pressure readings periodically as the patient goes about his or her daily affairs.

The standard blood pressure measuring device against which all others are compared is the familiar mercury sphygmomanometer, an inflatable cuff connected to an upright column of mercury. This device does not need to be recalibrated periodically as do other ones.

Home blood pressure measuring devices may be of the mercury type, but more often are an aneroid manometer (which works by air pressure) or an electronic device. These devices are reasonably accurate if calibrated annually against a mercury sphygmomanometer.

Electronic devices with a digital readout are the easiest to use since they do not require the use of a stethoscope to determine the blood pressure. They are extremely sensitive, which may be a disadvantage in some cases. If the cuff is not placed properly or the patient moves his or her arm during the measurement, an inaccurate reading will occur. These devices need to be calibrated more frequently than other ones.

The committee report on stationary automated blood pressure devices states coin-operated and free machines are inconsistent. The date of calibration is usually not known to the patron using such a machine. At best, the blood pressures reported by these machines may vary from 5 to 10 mmHg from reading to reading, with the error usually on the high side. Therefore, users of these machines should not base any action to reduce blood pressure on them. The machine reading should be confirmed by a careful clinical assessment of blood pressure.

Ambulatory blood pressure monitoring machines are used only under the supervision of a physician. The device is worn for an extended period of time by the patient so that blood pressure readings may be obtained at specified times during the day or night. Blood pressure machines may be called either automatic, in which the machine measures and records the blood pressure, and semiautomatic in which the patient must inflate the cuff. The attached recording device is battery powered which enables the patient to go about his or her daily activities with out being tethered to an electrical outlet. Patient education is essential with the use of these devices, as any motion during the reading results in false values.

Self-administered blood pressure tests may prove valuable in spite of the problems associated with some of the devices. Patients previously unaware of their condition may be discovered and may be brought under treatment. Also, for patients with only borderline hypertension, the data collected periodically may provide blood pressure patterns by time of day which may assist in arriving at an effective treatment program.

For individuals diagnosed as having hypertension, periodic at-home determinations help to monitor blood pressure levels so that the effectiveness of treatment can be assessed and adjusted if needed. Self-measurement also is a means for the patient to participate in his or her treatment regimen and perhaps reduce the number and frequency of visits to the physician's office.

Home blood pressure measuring is a mixed blessing, however. Elevated readings obtained on a home device may send a patient hurrying in to see a physician unnecessarily, or repeated false negative readings on the machine may lull the patient into believing that he need not seek treatment.

Overall, the committee concluded that home blood pressure measurement may be more suitable for some patients than for others. Some individuals may become unnecessarily alarmed at the normal fluctuations of blood pressure associated with the daily routine. Overreaction to such fluctuations may result in distress and inappropriate self-adjustment of medication without proper medical consultation. Also, because the measurement by the machine may be influenced by factors such as noise in the environment, movement by the patient or improper size or placement of the cuff, the patient must be educated about the use of the device and the meaning of the results.

The committee's recommendations for use of the device are designed to allow consumers to obtain maximum benefit from home blood pressure measuring devices. Users should be advised to consult their physicians about an elevated reading and, plainly written instructions should be available to provide details about obtaining blood pressure. The health care professional who advises the patient to obtain a blood pressure measuring device also should provide information on where to get the instrument calibrated initially and periodically and how to keep proper records.

The patient should realize that a reading of 140/90 mmHg or above is considered elevated, although a single such reading does not constitute a diagnosis of hypertension, but is a sign that additional observation is necessary. Above all, persons who have been diagnosed as having hypertension should remain on their prescribed treatment programs and report their blood pressure readings to their physician rather than making adjustments in their drug regimen on their own.

Along with elevated blood cholesterol and cigarette smoking, hypertension is still considered one of the major risk factors for heart attack. It is the predominant risk factor for stroke. To assess the risk associated with various levels of blood pressure, the NHBPEP Coordinating Committee formed a working group to examine the statistical and epidemiologic risks associated with high blood pressure.

They reported that the risks of morbidity and mortality related to blood pressure levels are difficult to define. Generally, the risk associated with high blood pressure is graded, with risk increasing as the blood pressure increases.

The working group also found that the previous categories of normal blood pressure, borderline hypertension and hypertension were inadequate. They therefore established three other categories based on the diastolic blood pressure.

A diastolic pressure below 80 mmHg is in the category of minimal risk. Individuals with readings in this range need no attention other than periodic measurement of their blood pressure to ascertain that it remains at this level.

Individuals with a diastolic blood pressure of 80 to 89 mmHg are considered to be at intermediate risk. This stratum of blood pressure alerts the clinician and the patient to the need for a reassessment of blood pressure at a shorter interval than would normally be the case. Although persons within this category probably would not be candidates for active drug therapy, certain preventive interventions can moderate the diastolic blood pressure. These interventions can include an assessment of risk factors, the reduction of which may benefit the patient in other ways (e.g., reduction of elevated blood cholesterol or beginning a systematic exercise program).

The final category is applied to patients with a diastolic blood pressure over 90 mmHg who are considered in the higher risk category. A second blood pressure determination at a later date that duplicates the original high reading is an indication to begin measures to bring the diastolic pressure down.

The data examined by the working group were derived from studies carried out in the United States or among population groups with similar lifestyles (such as Australia and Sweden). These recommendations may have only limited application to other ethnic groups whose genetic heritage, habits or lifestyles differ significantly. These recommendations are directed at the population aged 30 to 70 years and should not be interpreted as being applicable to children or to the elderly. The need for additional research among those groups as well as among blacks and other segments of the population is evident.

National Institute of Child Health and Human Development

Hypertension during pregnancy is a major cause of sickness and death in both the mother and fetus. Whether preexisting or pregnancy induced, hypertension is associated with a variety of disorders, the most common being preeclampsia. If uncontrolled, it can develop into eclampsia, an acute, sometimes fatal condition occurring in late pregnancy that is characterized by high blood pressure, convulsions, and/or coma. The development of an effective therapy has been severely hampered by the lack of understanding of the alterations in normal processes that occur in hypertensive pregnancies. Therefore, a portion of the research program of the National Institute of Child Health and Human Development (NICHD) focuses on this crucial subject.

Grantee Dr. James E. Metcalfe at the University of Oregon Health Sciences Center in Portland is conducting a study of the variations in cardiac output that occur during different phases of pregnancy. Output rises in midpregnancy, only to fall to nonpregnant levels in late pregnancy. Electrocardiographic studies of women throughout pregnancy and after delivery show that the ability of the heart to contract is the same in late pregnancy as after delivery. Researchers speculate that the filling pressure of the heart is impaired in late pregnancy because of reduced blood flow through the veins. Further studies will seek to determine whether this venous impairment is attributable to obstruction by the enlarged uterus, changes in the veins themselves, or both.

The metabolism of hormones probably plays an important part in hypertension. Dr. Greti Aguilera, an NICHD intramural scientist, is studying the renin-angiotensin system in rats and primates. Renin is a hormone that raises blood pressure by causing the body to retain salt, and thus, to retain fluid. It also causes the formation of angiotensin, which constricts blood vessels. One form of angiotensin (AII) regulates circulatory homeostasis (equilibrium in the body) and the secretion of aldosterone, a hormone produced by the adrenal gland which raises blood pressure. The adrenal gland has been found to be more sensitive to AII when sodium is restricted. Moreover, it has been established that a recently discovered cardiac peptide inhibits aldosterone production. Studies are under way to determine the role of this cardiac peptide (a compound of two or more amino acids) in regulating adrenal sensitivity to AII in several physiological conditions.

Additional research focuses on changes in the metabolism of prostaglandins, fatty acids that affect hormones. NICHD grantee Dr. Kenneth E. Clark at the University of Cincinnati in Ohio, has found that infusion of one type of prostaglandin in an animal model, the sheep, causes hypertension. Another prostaglandin (PGI_2) reduces blood pressure in hypertensive pregnant animals, but it also was found to cause hypoxia, or reduced oxygen flow, to the fetus. Clinical investigators have recently suggested that PGI_2 might be an effective treatment for pregnancy-induced hypertension in humans. However, this animal study indicates that such treatment may carry the risk of damage to the fetus because of hypoxia.

Fetal hypoxia, which often appears with maternal hypertension, and can cause developmental problems, is being studied by a team of researchers at an NICHD-established Perinatal Emphasis Research Center. Dr. Stanley L. James and colleagues at Columbia University in New York City are searching for a marker by which physicians can determine the presence of fetal hypoxia. They found that when oxygen is low, the fetus produces vasopressin, a hormone that increases blood pressure. The vasopressin is then excreted in the fetal urine and can be detected in amniotic fluid. Other studies show that fetal production of vasopressin in cases of hypoxia contributes to the maintenance of blood volume.

In other hypertension-related research supported by the NICHD, scientists are looking at whether use of oral contraceptives has any long-term cardiovascular effects. The NICHD is currently supporting several large contract studies in this area. One, specifically related to hypertension, is being conducted by Dr. Ronald T. Burkman at The Johns Hopkins University in Baltimore. The Hopkins study is a long-term project that began in 1983 to examine the extent to which women vary with regard to the levels of contraceptive hormones in their blood while using the same oral contraceptive formulation. The investigators examine whether these levels are predictive of oral contraceptive-induced changes in some risk factors for cardiovascular disease, such as high blood pressure.

National Institute on Aging

Approximately 50 percent of older black Americans and 40 percent of older white Americans have some form of hypertension. In view of the anticipated dramatic growth of the older population in this country, the National Institute on Aging supports a number of studies aimed at reducing the incidence of this disorder and at creating better treatments for those with hypertension.

In one study of treatments for high blood pressure, Dr. Bernard Engel at the NIA's Gerontology Research Center in Baltimore is studying a "Behavioral Stepped-Care" program including blood pressure self-regulation and relaxation techniques as methods for lowering blood pressure. There are several advantages in using behavioral treatments in combination with drug therapy in older patients. First, drug dosages are more difficult to select in older persons. Second, the problems of drug interactions and adverse drug effects in this age group are well known.

Dr. Engel has studied two groups of patients who are receiving drug treatment for high blood pressure. Patients in the behavioral therapy group are trained to monitor their blood pressure on a regular, daily schedule. Blood pressure is also checked by qualified professionals. If blood pressure is reduced below a predetermined level, medication is reduced; for those patients whose blood pressure is maintained at acceptable levels, medication is stopped entirely. A control group (patients receiving medication therapy but no behavioral therapy) is also being followed.

The early results show that patients receiving behavioral therapy have greater drops in blood pressure readings compared to control patients and thus are able to reduce and, in some cases, even discontinue drug treatment. These patients are able to sustain lower pressures, even after significant reductions in medications.

Another benefit derived from using behavioral treatments in combination with or in place of drug treatments is the cost savings to the patient. In view of the large number of drugs prescribed for this age group, medication costs for older adults are often significant.

Another aspect of high blood pressure is being studied by NIA-supported investigators at Harvard Medical School in Boston. There, researchers have shown that patients with high blood pressure tend to have greater drops in pressure when standing than do patients with normal pressure. Drs. John Rowe and Lewis A. Lipsitz have concluded that syncope (fainting) may be an additional, and previously unsuspected, consequence of high blood pressure in older persons, and might in some cases be prevented by antihypertensive medication rather than aggravated by such treatment as has generally been assumed. Syncope, which usually results in a fall, is a serious occurrence in older persons. Falls are a leading cause of serious injury and often permanent disability in this age group. Further studies are needed to determine if, in fact, control of hypertension lowers the risk of syncope.

Division of Research Resources

High levels of the hormone aldosterone are known to cause hypertension and deplete the potassium in the body. About 60 percent of the patients with this disease, called hyperaldosteronism, have aldosterone-producing tumors in their adrenal glands. The remaining 40 percent of the patients have been said to have the idiopathic (of unknown cause) form of the disease, because their hormonal imbalance could not be explained.

Recently, however, investigators at the University of Virginia Medical Center in Charlottesville found an agent that may cause the high levels of aldosterone in at least some of these patients. In studies performed in collaboration with Dr. Subha Sen of the Cleveland Clinic Foundation in Ohio, Dr. Robert M. Carey, associate director of the Division of Research Resources (DRR)-supported University of Virginia General Clinical Research Center (GCRC), and his colleagues found elevated levels of a glycoprotein (a protein-carbohydrate compound) called aldosterone-stimulating factor (ASF) in the urine and blood of seven patients with idiopathic hyperaldosteronism.

Approximately 51 of the 78 GCRC's, which are supported by the NIH Division of Research Resources, are conducting research into hypertension. Each year scientists conduct thousands of studies in GCRC's, which are located in major U.S. medical centers. More than 80 percent of the extramural inpatient research care funded by NIH takes place in these centers. In addition, extensive outpatient research is also carried out.

Dopamine, the vital neurotransmitter that is inadequately produced in certain critical areas of the brain in patients with Parkinson's disease, may lower the production of ASF, according to researchers at the Virginia GCRC. Previous studies by Dr. Carey and his colleagues, as well as by other scientists, have shown that dopamine reduces the excess production of aldosterone sometimes triggered by hormones from the kidney and other tissues. Also, because ASF levels appear to be elevated only in patients with the so-called idiopathic form of hyperaldosteronism, the glycoprotein may be in a diagnostic marker for identifying patients whose disorder is not caused by a tumor.

Another cause of high blood pressure involves calcium. An excess of calcium in the body can cause blood vessels to constrict, increasing blood pressure and reducing blood flow to the kidneys. Recently scientists at the University of Southern California (USC) GCRC in Los Angeles discovered a natural system that regulates blood pressure in a way that protects against the damaging effects of excess calcium.

Studies in normal volunteers showed that even small rises in blood levels of calcium stimulate production of a compound called prostacyclin, which helps maintain normal blood pressure. It also promotes blood circulation to vital organs and decreases the tendency of blood platelets to stick together, a phenomenon that can lead to a stroke or a heart attack. In the GCRC study, low doses of calcium produced no apparent change in blood pressure or blood flow to the kidney as long as the body released prostacyclin normally. But when the subjects received an anti-inflammatory drug such as ibuprofen, which blocks the release of prostacyclin, the same low dose of calcium caused an increase in blood pressure and a drop in blood circulation to the kidneys.

According to Dr. Jerry Nadler, a DRR grantee at USC, the research implies that some people who do not know they are hypercalcemic, because prostacyclin prevents clinical signs of the disease, may become hypertensive if they take drugs that block prostacyclin release. They might then be at risk of developing kidney damage or heart disease. Dr. Nadler and his GCRC colleagues are now examining these potential risks in patients known to have problems regulating body calcium.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

HYPERTENSION

The total prevalence of hypertension in the United States population 18-74 years of age was determined in the National Health and Nutrition Examination Survey (NHANES I) of 1971-74 with further data on hypertensive heart disease obtained on adults 25-74 years of age. These NHANES studies also permit comparison of blood pressure levels over time, providing population-based broad program evaluation information as well as data for epidemiologists studying the decrease in cardiovascular-related mortality rates.

In the second examination program on the probability sample of the population 18-74 years of age (NHANES II), data on the prevalence, severity and person's awareness of their hypertensive condition was again collected as an aid to the National Hypertension Control and Research programs in monitoring progress in the control of this condition. Data on hypertension were also collected in the Hispanic HANES.

Published data from the NHANES II, which covered the period 1976-80, indicate that there has been increased awareness, treatment, and control of hypertension during the 1970's. Approximately 25.1 million United States adults ages 25-74 years were estimated by examination and interview to either have elevated blood pressure or be on hypertensive medication, a rate of 22.0 per 100 persons in that age group. The prevalence of hypertension among adults has not changed significantly since 1960-62 except for an increase among white men. However, among those with hypertension, the percent never diagnosed by a physician as having hypertension or high blood pressure has dropped significantly. This increase in awareness has been accomplished by an increase in the proportion of hypertensives who reported they were currenly taking antihypertensive medication. From Hispanic HANES results, about 23% of the adult Mexican-American men and 19% of the adult Mexican-American women were found to be hypertensive. Although three-quarters of the hypertensive women knew about their hypertension, nearly one-half of the hypertensive women were not receiving treatment, and two-thirds of them did not have their conditions under control. .The profile was worse for men. Only 40% of the men were aware of their hypertension, 83% of them were not receiving antihypertensive medication, and, as a result, 92% of the hypertensive men had uncontrolled hypertension.

The National Ambulatory Care Medical Care Survey (NAMCS), another program of the Center, reported that patients with essential hypertension made an estimated 28.8 million visits to office-based physicians in 1981. During these visits there were about 45.3 million mentions of drugs, either new or continued, offered by the physician, for an average of 1.57 drug mentions per visit. The NAMCS collected detailed data on drug utilization for the first time in 1980. The survey was done annually from 1973 through 1981. The most recent survey was conducted in 1985.

In 1983, the National Health Interview Survey (NHIS) collected data on the prevalence of high blood pressure (hypertension) for the civilian, noninstitutionalized population of the United States. The total number of persons of all ages who reported having high blood pressure was 27,813,000. Of the different age groups, the highest rate was for those 65 years of age or older (387.9 per 1,000 persons). The rate of female groups combined reporting high blood pressure was higher than for males, 137.4 and 104.1 per 1,000 persons, respectively. The NHIS has been collecting hypertension data on a continuing basis since 1978. In addition, during 1974, the survey collected extensive supplemental data on hypertension for persons 17 years of age and over. The National High Blood Pressure Education Program was a major impetus for collection of these data to aid in their goal to lower the morbidity and mortality associated with hypertension. A detailed discussion of the extent of the problem of hypertension, including factors which increase the risk of hypertension, appeared in *Health, United States, 1976-1977*.

According to the 1984 National Hospital Discharge Survey, an estimated 415,000 patients were discharged from short-stay hospitals in the United States with a first-listed diagnosis of hypertensive disease. The average length of stay for these patients was 6.5 days. Females accounted for 57 percent of the discharges and patients 45 years and over accounted for 84 percent of the discharges.

There were an additional 3.0 million hypertensive disease diagnoses (other than first-listed). Although some of these diagnoses were associated with patients who had a first-listed diagnosis of hypertensive disease, the majority of these patients had a non-hypertensive disease as first-listed diagnosis.

LONG-TERM CARE

Obligations

	1983 Actual	1984 Actual	1985 Actual	1986 Appropriation	1986 After Sequestering	1986 Revised Estimate	1987 Estimate
Public Health Service:							
Health Resources and Services Administration: Bureau of Health Professions..............	1,561,995	846,391	448,959	715,770	693,042	91,849	—
Alcohol, Drug Abuse, and Mental Health Administration...........	10,200	548,000	700,000	600,000	470,000	527,000	549,000
Office of the Assistant Secretary for Health: Nat. Ctr. for Health Services Research: Grants & Contracts......	640,105	293,282	1,222,955	586,065	586,065	586,065	551,088
TOTAL, PHS..........	2,212,300	1,687,673	2,371,914	1,901,835	1,749,107	1,204,914	1,100,088
Health Care Financing Administration............	11,000,000	8,915,000	9,155,000	9,985,000 1/	9,985,000 1/	9,985,000 1/	10,593,000 1/
Office of Human Development Services..............	4,600,000	2,700,000	4,500,000	900,000	900,000	900,000	— 2/
TOTAL..............	17,812,300	13,302,673	16,026,914	12,786,835	12,634,107	12,089,914	12,242,088

1/ These amounts represent the estimated Federal share of Medicaid payments for Long Term Care under current law.

2/ Level cannot be determined at this time.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Bureau of Health Professions

LONG TERM CARE

Under the Area Health Education Center program five awardees, the Universities of North Carolina School of Medicine, Massachusetts, and Michigan State, Oklahoma Community AHEC, and Eastern Virginia Medical Authority received a total of $207,892 for long term care educational activities, estimated to impact 8,940 individuals in FY 1985. The largest award was made to University of North Carolina School of Medicine for $180,000.

Seven General Internal Medicine/General Pediatrics Residency programs also indicated that they would provide long term care training in FY 1985. Two programs, the University of California - Davis and Mercy Hospital and Medical Center, will receive $[illegible] and $9,[illegible], respectively.

The Division of Nursing supports special project grants to develop training methods for nurses aides and orderlies in long term care. The Nursing Research grant program provides for the studying of home management of hypertension; children with chronic illness; kidney dialysis; quality of care to the elderly, nursing personnel in nursing homes; acute confusional states in hip fracture patients; palliative care to cancer patients; and quality of life in patients with chronic illness.

Under Family Medicine Training programs in FY 1985, two predoctoral and four graduate grantees indicated that individuals would be trained in long term care issues. East Carolina University's Faculty Development Training program will also provide training in this particular area.

Six Physician Assistant Training programs [illegible] have activities aimed at exposing students to the issues of long term care.

In FY 1983 and FY 1984 an interagency agreement between National Center of Health Statistics (NCHS) and Bureau of Health Professions was funded for NCHS to obtain data on health personnel staffing and factors affecting registered nurse recruitment and retention as part of NCHS' National Nursing Home Survey.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute of Mental Health

Long-Term Care

In the mental health field, long-term care issues relate primarily to people with a severe and persistent mental or emotional disorder that seriously impairs their ability to function in their primary social and vocational roles--the population known as experiencing chronic mental illness.

Included in this population, of which the largest number are adults, are significant numbers of children, approximately 400,000 to 800,000, as well as such special populations as the aged, the incarcerated, and the homeless. It has been estimated that approximately three million persons age 18 and older suffer from severe or persistent mental disorders. Of these, 2.4 million are moderately to severely disturbed, and 1.7 million suffer prolonged, severe disability. Of this number, it is estimated that between 1.0 and 1.1 million reside in private households. A new group of long-stay patients in State mental hospitals appears to be replacing the older group of long-stay patients as that latter group ages, is moved to nursing homes, and dies.

There are approximately 1.3 million patients in certified nursing homes, of which approximately 300,000 have a primary mental disorder (depression, presenile and senile dementias, psychoses). An additional 450,000 patients exhibit senility without psychosis. There has been a dramatic shift in the locus of care for the mentally ill elderly from State and county mental hospitals to nursing and personal care homes.

Intramural Research:

In FY1985, NIMH continued evaluation activities associated with the NIMH Community Support Program (CSP). A contract project was completed that field tested State and service area performance measures for use by States in self-assessments of programs for the chronically mentally ill. This project was the third in a sequential approach to CSP evaluation. The primary objective was to further refine and field test the CSP performance measurement system developed through earlier exploratory and short-term evaluations. It focused on a field test in 20 States and 94 local service areas to determine the feasibility and utility of State and Service Area Questionnaires as self-assessment tools.

A purposive sample of States was selected based on two stratifying variables. The first was the date of the State's initial Federal CSP grant award, with States receiving their first funds in 1977 classified as "old grantees" and States entering the program in 1982 classified as "new grantees." The second stratifying variable was State population density to ensure that both high and low density States were included in the sample. Five States of each type were selected, and each completed a State Questionnaire.

The target sample of local service areas (i.e., mental health catchment area or other planning/service providing area) included 120 areas--six from each of the 20 States. Systems development was selected as a major stratifying variable for local service areas in order to provide an adequate test of the Service Area Questionnaire in highly developed as well as poorly developed systems. A total of 94 service areas were selected by States, including 45 well developed sites and 49 less well developed sites.

A number of factors were considered in order to assess instrument adequacy. Review of missing information, out of range responses, internal consistency edit checks and estimation procedures used to derive quantitative responses were among the methods used. The instruments were found to be useful for one of their intended purposes--as self-assessment tools. They will provide States and communities with a technology for assessing and monitoring their progress over time in meeting the needs of the chronically mentally ill.

The field test of self-assessment instruments afforded the opportunity to analyze the CSP performance measures across States and service areas. The performance measures are organized around major outcome areas. These outcome areas are broad areas which are considered to be key areas of focus for measurement of CSP's success.

The first outcome area assessed by the State-Level Questionnaire is "definition of the State-level organizational locus for CSP-related activity." The analysis revealed that the new grantees tend to have a separate CSP unit, while the old grantees tend to assign responsibility for CSP activities to individuals within other units of the State mental health agency. Another measure in this outcome area assesses the State's "strategy" or approach to the challenge of Community Support System (CSS) development. The field test revealed that both old and new grantees have focused on "modifying the mental health system" as a primary strategy for promoting CSS development.

A second outcome area is "State-level mobilization." The findings showed that the vast majority of States reported that they have made significant gains in all system change improvement areas during the reporting period. However, States have had the most success in modifying their mental health systems, and have been less successful in their efforts to modify the larger health and human services system.

A third outcome area measures "resource mobilization" or the availability of resources for services and support of the CSP population. The field test results show that substantial sums of money are being spent by States for services to the mentally ill. However, it appears that State mental hospitals continue to receive disproportionately high shares of State mental health budgets.

The major outcome area assessed by the Service Area Questionnaire is "local CSS development." A rating system was designed whereby local service areas estimate the extent to which they are meeting the need for each of the CSS components. The CSS ratings showed that most local service areas are meeting much of the need for crisis assistance and mental health services. The most deficient of the CSS components across sites appeared to be rehabilitative and supportive housing, which is consistent with State-level results. Results also show that the Service Area Questionnaire may, in fact, discriminate between well and less well developed sites. For each of the CSS components and the composite CSS rating, well developed sites rated slightly higher than less well developed sites.

In FY1985, the first data collection phase was completed for a second contract project to perform a cross-sectional description and a longitudinal cohort analysis of CSP clients. Information from this project will be available early in FY1986. Also in FY1985, NIMH implemented a contract project to field test in two States a cost-outcome methodology for the CSP. Field work is expected to commence on this latter project early in FY1986.

NIMH has also played a major role in developing research on the homeless mentally ill. NIMH staff have consulted with a large number of potential grantees and researchers, including grantees of the Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services (DHHS); and have made presentations at major meetings, such as the annual meetings of the National Council of Community Mental Health Centers and the National Council on Social Work Education.

Extramural Research:

The special grant announcement jointly sponsored by the Office of State and Community Liaison and the Division of Biometry and Epidemiology in FY1983 on State Mental Health Service System Research on the Chronically Mentally Ill had no followup research initiative. Of the eight projects funded under this grant announcement, four have been completed, with final reports submitted. The remaining four are anticipated to be completed in FY1986.

One of the completed projects from this special grant announcement was a research project administered by Dee Roth of the Ohio Department of Mental Health, the funded agency for this grant. The research grant was entitled, "Prevalence of Mental Health Problems Among Homeless People." The study was carried out to understand more thoroughly the characteristics of the homeless population, specifically those who were found to be mentally ill, and the relationship between mental health policies and procedures, and homelessness among the mentally ill.

A number of studies have been conducted which have attempted to describe the homeless population. These studies have generally been limited to shelter populations and soup kitchen users in urban areas; frequently, identification of the mentally ill has been based on a prior psychiatric inpatient experience. The Ohio study addressed these limitations of previous studies. Both rural and urban counties were included in the Ohio sample; shelter and street people were sampled; and selected scales of the Psychiatric Status Schedule were used to obtain data on psychiatric symptoms. This permitted the researchers to identify and classify cases according to clinical severity.

From a sample of nearly 1,000 homeless persons, economic factors emerged as being the major cause of homelessness for half of the sample. This was true of both urban and nonurban homeless people. Rates of physical problems, psychiatric problems, and psychiatric hospitalization did not differ substantially between the urban and nonurban homeless, although urban respondents were more likely to report problems with alcohol.

About 30 percent of the homeless persons had experienced at least one psychiatric hospitalization; about 18 percent had been hospitalized in a State mental hospital. Of the total respondent group of homeless persons, slightly more than 7 percent had last been discharged from a State mental hospital between 1960-1980, while another 11 percent has last been discharged from such hospitals in the four years between 1981-1984. About 31 percent of the total respondent group currently required some form of mental health services, based on data from the Psychiatric Status Schedule. About half of these had been hospitalized in a mental hospital in the past. Generally, these results suggest that additional research is needed to address the linkage between deinstitutionalization, mental illness, and homelessness through prospective, longitudinal cohort studies of homeless persons and persons discharged from State mental hospitals.

A second completed research project under the special grant announcement was carried out under the direction of Edna Kamis-Gould, Ph.D., Chief, Bureau of Research and Evaluation, New Jersey Division of Mental Health and Hospitals and co-principal investigator, Arie P. Schinnar, Ph.D., Professor, Wharton School, Philadelphia, Pa. The project was titled, "Cost Effectiveness of Partial Care/Hospitalization Programs for CMI, Structured under Different Auspices, Organization Complexity, and Funding."

Partial care programs (also known as partial hospital, day hospital, and day treatment programs) experienced rapid national growth following Community Mental Health Center (CMHC) legislation in 1963, which included partial care as one of the essential services to be provided by a federally-funded CMHC. Not only did partial care programs grow in number, but they were established under different auspices, and had different organizational arrangements. In response to the multiple treatment needs of a diverse population of mentally ill, these programs diversified with respect to intensity and type of program, size, staffing, client mix, and funding mix. The task confronting a funding agency to assess the efficacy, productivity, cost efficiency, and cost effectiveness of the partial care programs supported by the agency is formidable, particularly since the programs differ along so many dimensions. Yet, if resources are to be allocated wisely among providers so as to eliminate or stimulate improvement in providers that are inefficient, unproductive, and ineffective, some method must be developed and employed to assist the funding agencies in their evaluative tasks.

This project introduced and developed a novel method, best-practice frontier analysis, to assess the efficiency, productivity, and effectiveness of the 54 partial care programs funded by the State of New Jersey. It was developed recently to evaluate public programs in health, education, and human services. This grant represented its first application to mental health. The characteristic of best-practice frontier analysis is that programs are compared only to each other. The best program is not the best in an absolute sense, but best only in relation to all the others in the comparison group.

Some of the highlights from the findings of this study are as follows:

1. Freestanding partial care programs are both more efficient and effective than hospital-based programs.

2. Patient care programs which are individualized for clients are less efficient but more effective than those that have a homogeneous program for all clients.

3. Partial care programs that receive a relatively small percentage of their funds from the State are more efficient but less effective than those which are largely supported by State funds.

4. Organizational characteristics were the main determinants of efficiency; client characteristics were the main determinants of effectiveness.

Planning and Demonstration (Community Support):

Initiated in 1977, the NIMH Community Support Program (CSP) works with States and localities to improve opportunities and services for adults with chronic mental illness. CSP focuses specifically on those adults who are inappropriately institutionalized in hospitals or nursing homes, and the larger number of such individuals who are living outside of hospitals without adequate housing or life support services.

In FY1985, continuation funding was provided to 35 States, 2 territories, and the District of Columbia. CSP funding has ended for the remaining 15 States, but efforts have been made, such as providing travel funds to attend meetings and conferences, to keep these States in the CSP network.

In FY1986, depending on availability of funds, approximately 14 new grants will be awarded to support local mental health services demonstration projects for two subpopulations of the long-term mentally ill--the elderly and homeless persons with long-term disabling mental illness. These new demonstration projects were authorized under the 1985 Amendments to the Public Health Service Act.

In FY1985, a new Rehabilitation Research and Training Center in mental illness was funded through an interagency agreement between NIMH and the National Institute on Handicapped Research, Department of Education.

The Seventh National Learning Community Conference was held in Rockville, Md., April 30-May 2, 1985, and focused on choices and challenges facing the CSP and the field in continuing to work toward improved services for the target population. Regional conferences were held in each of the 10 DHHS regions. One State CSP Project Directors' Meeting was held in Chicago, Il., October 16-19, 1985, to provide a forum for problem-solving and information sharing among CSP Project Directors. The first national conference of ex-mental patients was held in Baltimore, Md., June 18-20, 1985.

Eight regional conferences, one State CSP Project Directors' Meeting, and the second national conference of ex-mental patients are planned for FY1986.

Rural issues continue to be a strong focal point of activity for projects in rural States, such as Utah, Nebraska, Iowa, Kansas, North Dakota, and Arkansas. Topics related to rural issues have been included in several of the regional conferences. In addition, a well-attended conference on developing CSSs in rural areas was held in Logan, Ut., in June 1985. A similar conference is planned for Arkansas in the spring of 1986.

The Joint Interagency Agreement between the NIMH and the Health Standards and Quality Bureau of the Health Care Financing Administration was terminated on December 31, 1984. This completed a period of 16 years of close affiliation between the two Federal agencies for the performance of Medicare surveys in psychiatric hospitals on a nationwide basis. The Health Standards and Quality Bureau has now assumed the responsibility for the conduct of Medicare surveys of State mental hospitals and the State Licensing and Certification agencies have assumed responsibility for the survey of nonpublic mental hospitals.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

THE NATIONAL CENTER FOR HEALTH SERVICES RESEARCH

Long Term Care

The National Center for Health Services Research and Health Care Technology Assessment (NCHSR) seeks to create new knowledge and better understanding of the processes by which health services are made available and how they may be provided more efficiently, more effectively, and at lower cost.

NCHSR is the primary source of Federal support for research on problems related to the quality and delivery of health services. NCHSR responds to the need for better data and information, new techniques, and innovative methods for improving health care delivery. NCHSR programs evaluate health services, assess technologies, and improve access to new scientific and technical information for research users. NCHSR's research is targeted to the needs of health care policymakers, including executive and legislative officials at Federal, State, and local levels; those who operate hospitals and other health care institutions; and individuals who are responsible for health care expenditures.

The NCHSR extramural research program provides support for investigator-initiated projects in health services research conducted at universities; nonprofit organizations in institutions, such as teaching hospitals; and by industry. The intramural research program conducts studies that have immediate as well as long-term relevance.

Division of Intramural Research

Long-Term Care Project

The Division of Intramural Research's Long-Term Care Project is conducting research on the financing and delivery of long-term care. Survey data collected by NCHSR are being compared to responses from an American Association of Retired Persons (AARP) survey to assess consumer interest in purchasing insurance for long-term care. Demand models are being estimated to help assess the market for such insurance. Other data requirements for developing long-term care insurance also have been examined and existing data sets are being explored for their usefulness in clarifying the feasibility and implications of alternative benefit features. Longitudinal data from a study of San Diego nursing homes have been used to examine the effect of multiple admissions on length of stay. These data are also being used to explore the clinical course of nursing home patients over time.

The San Diego data are from a recently completed research experiment to test the effectiveness of case-mix incentive payments to encourage more appropriate use of nursing homes, better outcomes in nursing home patients, and reductions of hospital backup. The study found that the tested reimbursement system did improve access for heavily dependent Medicaid patients but did not affect patient care outcomes. Secondary analysis of these data will further clarify considerations for successful implementation of nursing home case-mix reimbursement.

Research is also being undertaken to determine the feasibility of modeling the major elements of the long-term care system at the state and local level. The goal is to establish a flexible framework that can be used to assess the consequences of alternative strategies for servicing the health care requirements of an aging population. Existing research and data on relevant issues will be analyzed as the initial basis for the modeling effort.

Health Services for the Aged Studies Program

The aging of the U.S. population has heightened public and private focus on the health, social, and residential services required by individuals who have lost the ability to function independently because of physical and mental impairments. The increasing risk, with age, of incurring such impairments, coupled with the rapid growth of the elderly will continue to be an important issue for public and private policies. The Health Services for the Aged Studies Program (HSASP) was initiated by NCHSR in 1985 to conduct research in three areas related to health, social and residential services for physically and mentally impaired elderly.

- Nursing Home Admission and Use
- Home and Community-Based Care
- Supply of Health, Social, and Residential Service

The HSASP completed two analyses in Fiscal Year 1985 which are of particular relevance to health policy for the elderly:

1. An analysis was completed on the private expenses for home-based long-term care for elderly with limitations in activities of daily living (ADL) and instrumental activities of daily living (IADL). Data for the study were available from the 1982 Long-Term Care Survey of noninstitutionalized elderly Americans. The study found that the amount of out-of-pocket payments expended were

associated with health status, family income and other personal characteristics of the disabled person. In addition, high amounts of out-of-pocket payments were strongly associated with "risk factors" of nursing home admission such as prior nursing home residency.

2. An analysis is being conducted on the informal caregivers of the disabled elderly residing in the community. Data from the 1982 Survey of Caregivers are being analyzed to provide a national profile of the informal caregiver network. Demographic and socioeconomic characteristics of the caregivers are being analyzed to identify who assumes the responsibility for the care of impaired elderly persons. Second, analyses to assess the level of caregiver burden is being conducted to determine the degree of emotional strain, the direct financial costs and the opportunity costs with respect to work and social responsibilities. Reports from these analyses will be available early in 1986.

In FY 1986, further analyses will be conducted on the home and community based care of noninstitutionally disabled elderly. One area will be a detailed analysis of the health characteristics of the disabled elderly, and how such characteristics predict the amount of informal and formal caregiving used. This analysis, which will use a merged file of the 1982 Long-Term Care Survey and the 1982 Survey of Caregivers, will control for other factors, such as income, living arrangement, and housing characteristics.

National Health Care Expenditures Study

The National Health Care Expenditures Study (NHCES) of the Division of Intramural Research engaged in a number of activities in FY 1985 which are of relevance to health policy for the elderly. Planning was begun for the 1987 National Medical Expenditure Survey (NMES), which will collect a substantial amount of new information on the elderly and long-term care. The NHCES group also published or completed a number of studies in FY 1985 based on the 1977 National Medical Care Expenditures Survey (NMCES).

NMES will have two primary components: a household survey of 14,000 households in the civilian non-institutionalized population and a survey of 13,000 residents of nursing and personal care homes, psychiatric hospitals and facilities for the mentally retarded.

The household survey will include an oversample of groups of particular policy interest: the elderly, blacks, Hispanics, the poor and near poor, and persons with functional limitations. In addition to the core data on use, expenditures, health insurance and sociodemographic variables, the 1987 NMES household survey will have a new focus on long term care. For example, data will be obtained on charges and sources of payment for both formal and informal caregivers and on various measures of health status and functional limitations of the noninstitutionalized long term care population.

The institutional population component will sample 700 nursing and personal care homes, 77[illegible] facilities for the mentally retarded, and 200 psychiatric hospitals. The resident sample of 13,000 patients has been designed to represent persons who were residents of such institutions on January 1, 1987 and persons who were admitted during 1987. Data will be obtained on health status and functional status; 1987 institutional charges and sources of payment; expenditures and sources of payment for care provided to sample patients by physicians, acute hospitals and other non-institutional providers during 1987; and length of stay. These data will be supplemented by information obtained from surveys of the next of kin or community respondents. Data will be obtained on the health status and functional limitations of sample patients prior to admission, characteristics of family members, and supplementary data on use, expenditures and sources of payment during 1987.

Studies published by members of the NHCES staff in 1985 include:

> Private Health Insurance of the Medicare Population and the Baucus Legislation; Cafferata, G.L.; Medical Care, 1985.
>
> The appropriateness of the benefits associated with the private insurance coverage of the Medicare population has been the subject of considerable concern. Section 507 of the Social Security Amendments of 1980, also known as the Baucus legislation, reflects public concerns about the level of benefits in relation to premiums, duplicative coverage, the complexity and difficulty of insurance terminology, and marketing abuses. Data from NMCES provided useful baseline data on the distribution of Baucus-like plans. In 1977, private insurance held by the Medicare population was more likely to cover inpatient than outpatient services and to emphasize "first dollar" benefits for long-term care. Multivariate analyses show that the distribution of Baucus-like insurance policies is highly associated with health status, source of insurance, region, and place of residence. The importance of state regulation, suggested in other research, may account for these patterns.

The Elderly's Private Insurance Coverage of Nursing Home Care; Cafferata, G.L.; American Journal of Public Health, 1985.

About 40 percent of Medicare beneficiaries had private insurance coverage of skilled nursing facilities (SNF) in 1977. Data from NMCES show that among such persons, about 85 percent had full coverage of Medicare's Part A copayments for days 21-100 but only 15.7 percent had maximum coverage of at least 365 days of care or a benefit of $100,000 or more. The most comprehensive benefits are found among persons with middle or high incomes; more generous first-dollar coverage is found in the North Central and South regions, and more generous maximums in the West.

Use of Home Health Services: Some Findings from the National Medical Care Expenditure Survey; Berk, M.L., and Bernstein, A.B.; Home Health Care Quarterly, 1985.

Data from NMCES are used to produce national estimates of the use of and sources of payment for home health care services for various demographic groups. The findings indicate that while age and health status are strongly associated with home health care use, the majority of persons using services are neither elderly nor limited in activity. In addition it was found that private insurance is only rarely mentioned as a source of payment for home health care.

Division of Extramural Research

NCHSR's Division of Extramural Research supported a number of projects in Fiscal Year 1985 on issues related to the elderly and long-term care.

New Starts in Fiscal Year 1985 include:

"ADL Change for Elderly at Risk of Institutionalization" (Katz)

A study of Activities of Daily Living (ADL) to determine which factors are associated with a change in functional status and the relationship between this change and utilization of health services by the elderly. It is expected that the ability to predict ADL change over time would allow communities to better assess the changing mix of residents and in turn better project their service needs and the community's future financial liabilities.

"Paying Physicians for Geriatric Care" (Butler)

A consensus conference to investigate the appropriateness of third-party payment of geriatric services in primary care settings by assessing the state of knowledge, identifying issues and questions needing further study, and discussing innovative payment methods. The approach will include a survey of 50 physicians regarding their encounters with aged patients. A report of the survey will guide the final topic selection and discussion at a conference of about 60 invited participants including practitioners in geriatric care, public and private payer and third-party representatives, and administrative, legislative, and research specialists in geriatric health economics and policy.

"Consistently High and Low Elderly Users of Medical Care" (Freeborn)

An analysis of the patterns of ambulatory care use by aged members of Kaiser's (Portland, Oregon) Health Maintenance Organization (HMO) to determine what factors differentiate consistently high and low users of service. Improved understanding of these factors could lead to the design of cost containment initiatives.

"Patterns of Medical Care Utilization" (Muller)

A study to test the hypothesis that changes in the amount of own-time (defined as non-work time) due to transition from full-time work to retirement increase the use of medical services by the elderly. The study will use several waves of the Social Security Administration's Retirement History Survey. The expected findings of this study will be relevant to public policy aimed at containing government expenditures and could contribute to changes in public policy related to employment possibilities for older workers.

Projects which were on-going in Fiscal Year 1985 include:

"Outcomes of Nursing Home Discharges" (Lewis)

A study to trace and analyze the paths of care of patients discharged from nursing homes. Patients will be followed to assess utilization of health care services post discharge and to ascertain status two years following admission to the nursing home. Preliminary work has identified the movement of nursing home residents back and forth between hospitals, nursing homes, other long-term care facilities, and patients' residences as a "continuing episode of care."

This study will attempt to refine and define a measure of the "continuing episode of long-term care" which should contribute significantly to long-term care policy.

"Computer-Based System for Long-Term Care and Research" (Zielstorff)

An implementation and evaluation of Computer Stored Ambulatory Record (COSTAR) in a community-based long-term care program for a group of elderly patients at high risk for re-institutionalization. COSTAR will be implemented to link three neighborhood health care centers to a hospital-based long-term care unit. This study is intended to develop both a model program of long-term care for the elderly and specific tools to enhance the provision of care.

"Quality of Life Factors in Geriatric Medicine Decisions" (Pearlman)

A research project designed to obtain insight into the perceptions of elderly patients, their physicians, and spouses regarding the quality of the patients' lives and its role in medical decisions. This will be done by gathering data through interviewer-administered questionnaires. Physicians will be sampled from community-based practices, nursing homes, a King County (Washington) HMO, and VA medical Centers in Washington and Oregon.

"Patient Slip/Falls Evaluation and Prevention" (Jackson)

An etiologic study of slip/fall incidents in hospitals comparing an estimated population of 1000 patients experiencing slip/falls and a random group of control patients of equal size who do not slip/fall. Data will be collected from medical records, staff and patient interviews, and neurologic exams. By identifying risk factors for slip/falls, interventions can be designed and implemented to reduce these risks.

One long-term care project was completed in Fiscal Year 1985:

"Correlates of Long-Term Care Expenditures and Service" (Estes)

A study to provide an inventory of State policies relative to Federal long-term care programs and to assess the effect of these policies on availability, utilization and public cost of long-term care services; and to develop a context within which State and Federal policy choices are examined. The project's Final Report consists of a series of papers covering estimates of the effect of state discretionary policy on the expenditures and utilization associated with a particular sector of the long term care continuum. A number of policy implications are suggested concerning interprogram coordination, nursing homes, home health, and income eligibility.

State and Local User Liaison Activities

During the summer of 1986, the NCHSR User Liaison Program will sponsor the second in a series of three and one-half day workshops on long-term care for the elderly. This activity is designed to address the problems and information needs of state legislators and executive branch officials from a variety of jurisdictions. Major issues to be addressed at the workshop include: the nature and magnitude of the informal long-term care support system; projections of growth in the elderly population and its impact upon informal support and public programs; alternative arrangements for the financing and delivery of long-term care services, such as community-based service programs and Social Health Maintenance Organizations; and private long-term care insurance as a financing option. The first workshop in this series took place in June 1985.

The User Liaison Program is currently in the process of designing a synthesis of research findings pertaining to alternative approaches for the financing and delivery of non-institutional long-term care services for the elderly. This document will provide a comprehensive, objective and critical analysis of our current base of knowledge in this area as that knowledge can be applied to the concerns, problems and responsibilities of state government officials.

Ongoing consultation is provided to State and local officials with respect to information and data needs on long-term care policy and managerial decisionmaking.

[illegible]

[illegible]

LONG-TERM CARE

The National Nursing Home Survey (NNHS), inaugurated in 1973, is a continuing series of national sample surveys of nursing homes, their expenses, residents, and staff. [illegible] under 65, 65-74, 75-84, and 85 and over, although some data are presented by 5-year intervals [illegible] characteristics, [illegible] and [illegible] of facility and staff characteristics [illegible] are also presented.

The initial NNHS was conducted from August 1973 to April 1974 and the second was conducted from May to December 1977. The 1977 survey was [illegible] to collect data on discharged residents [illegible] the facilities, communication [illegible] charge [illegible] received by residents. [illegible] published are "The National Nursing Home Survey: 1977 Summary," [illegible] Nursing Home Residents, Health Status, and Care Received [illegible] and "Employees in Nursing Homes [illegible] Health and Health Care Use." [illegible] available to the general public.

The [illegible] could be obtained for five States. [illegible] long-term care utilization and in the characteristics [illegible] nursing home [illegible] differences. [illegible] of long-term care systems [illegible] evaluating these systems. [illegible] *Health, United States, 19*[illegible]

The third NNHS was [illegible]

HEALTH CARE FINANCING ADMINISTRATION

Long Term Care

The mission of HCFA is to promote the timely delivery of appropriate, quality health care to its beneficiaries—approximately [illegible] million aged, disabled and poor Americans.

Medicaid and Medicare are the principal sources of funding for long term care in the United States. The primary types of care reimbursed by these programs of HCFA are skilled nursing facilities (SNFs), intermediate care facilities (ICFs), and home health services.

HCFA's Office of Research and Demonstrations (ORD) conducts studies and projects that demonstrate and evaluate optional reimbursement, coverage, eligibility and management alternatives to the present Medicaid and Medicare programs. ORD also assesses the impact of beneficiary access to services, health care providers and the health care industry.

DEMONSTRATION ACTIVITIES

In 1985, HCFA continued a number of demonstrations aimed at testing the effectiveness of community-based and in-home delivery systems for long term care services. These projects focus on the coordination and management of an appropriate mix of health and social services directed at individual client needs. HCFA also initiated the development of demonstrations which will test the cost effectiveness of prospective payment approaches for home health agencies.

Studies and demonstrations are being conducted to assess the impact of new reimbursement strategies to promote cost containment and foster quality of care. Efforts are also underway to identify more effective long term care quality assurance techniques and to improve the statistics and baseline information upon which future assessment of needs, problem identification and policy decisions will be based.

DEMONSTRATION PROJECTS AND INITIATIVES - 1985

National Long Term Care Channeling Demonstration Program

This intradepartmental effort was launched in September 1980 in an attempt to test the ability of community-based long term care projects to address many of the inefficiencies in the existing long term care system and assess the factors which influence their structure. The program included the close cooperation of HCFA, the Administration on Aging, and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) which was designated the lead agency in the effort. A steering committee of senior policy officials in these agencies was established under the chairmanship of ASPE to set broad goals and provide policy guidance regarding the program. A management team also was established, composed of senior staff in each participating agency, which had responsibility for providing technical direction and management on all aspects of the program.

The National Long Term Care Channeling Demonstration Program included the following two components:

1. Operational Design

The term "channeling" refers to the organization or operating system required in a community to insure that a client receives the long term care services he/she needs. Each project site in the national demonstration provided outreach/case finding, screening, comprehensive client assessment and case management.

Ten States were awarded contracts to participate in this demonstration program. Five States were designated as basic model projects in which channeling sites would provide only the core channeling functions: outreach, screening, assessment and case management. In addition, these sites were also awarded a specific amount of gap-filling service funds. The five basic model States are Maine, Kentucky, New Jersey, Texas and Maryland. Sites in these States began serving clients in February 1982.

The remaining five States, Pennsylvania, Ohio, Massachusetts, Florida and New York, were designated complex model projects. These projects modified the basic model approach by adding three program elements: expanded Medicare and Medicaid service coverage, authorization to approve reimbursement for services and limitations on per capita expenditures. By June 1982, the complex model sites began serving clients.

The demonstration was planned to build its caseload and maintain operations through September 1984. At that time, the project began discharging clients and phasing out the demonstration. All demonstration activities ended on March 31, 1985. Project sites prepared detailed phase-down plans in order to ensure that adequate alternative arrangements could be made for project clients.

2. Evaluation

A contract was awarded to Mathematica Policy Research, Inc. to conduct the evaluation. Mathematica collected uniform data from the 10 projects on client characteristics, service utilization, care and administrative costs. In addition, the evaluator assisted the projects in utilizing procedures for randomizing the potential client population into experimental and control groups. The total research sample was comprised of 4,993 clients which included 2,180 control group participants. In 1983, Mathematica produced a process analysis report that described the early planning and implementation experience of the demonstration. A series of reports focusing on different outcome measures will be prepared in early 1986. The final evaluation report is due in the spring of 1986.

AFDC Homemaker/Home Health Aide Demonstration

Section 966 of P.L. 96-499, the Omnibus Reconciliation Act of 1980, authorized the Secretary to enter into agreements with States for the purpose of conducting demonstration projects for the training and subsidized employment of AFDC recipients as homemakers and home health aides. During this 4-year demonstration, each State trains AFDC recipients as homemaker/home health aides to provide supportive services to elderly and disabled individuals who without these services would require institutionalization. The Medicaid program pays for the costs of the demonstration project, including the wages and employment costs of the AFDC participants. The Federal Medicaid match was increased to 90 percent as an incentive for State participation. The project includes a 6-month planning and developmental period, a 3-year operational phase and a 6-month wind-down period for the purpose of final reporting and evaluation. The operational segment of the demonstration began in January 1983. At that time, the States began the process of recruiting and selecting AFDC recipients to be trained as homemaker/home health aides. In the past 3 years, more than 3,500 AFDC recipients have been trained. These aides have provided the services authorized under this demonstration to over 8,8[illegible] individuals identified as being at risk of institutional care. The seven demonstration States are Ohio, New Jersey, Arkansas, Texas, South Carolina, New York and Kentucky.

Two major issues will be examined in this demonstration:

o the extent to which training AFDC recipients as homemaker/home health aides is feasible and results in continuing, unsubsidized, productive employment for the trainees; and

o elderly or disabled individuals who [illegible] these services, results in a lower use of institutional care, given the assumption that they would be reasonably anticipated to require institutional care.

In terms of expected results, three phases emerge: 1) the first phase will examine feasibility issues such as how many and what kind of AFDC recipients apply and are accepted into the program, how effective is the training and whether the availability of subsidized services expands the homemaker service population; 2) in the interim phase, the employment status of the trainees and the institutional status of the service recipients will be investigated (e.g., do trainees continue in the program, what services do clients receive and for how long?); and 3) the final evaluation phase will thoroughly examine the net cost-effectiveness of the program in reducing welfare dependency and institutionalization and costs for service clients. Final results are expected by December 1986.

Texas, "Modification of the Texas System of Care for the Elderly: Alternatives to the Institutional Aged"

The Texas Department of Human Resources (DHR) is in its sixth and final year of a demonstration project which is designed to reduce the growth of nursing homes in Texas while at the same time expanding access to community care services for needy individuals. The demonstration was initiated as a result of a State legislative mandate which required DHR to eliminate one of the two Medicaid intermediate care facility (ICF) levels of care (the ICF II level) and provide community based services to deinstitutionalized patients. For individuals who are deinstitutionalized, a care plan is developed and arrangements for in-home services through community service providers are made. The following services are provided: Medicaid Home Care Benefits, Medicaid Personal Care Benefits, Title XX Adult In-Home Services, and Section 1115 Waivered Community-Based In-Home Supportive Services.

Substantial progress has been made over the past 5 years in implementing the project. Of the 13,452 individuals in the ICF-II Cohort group in March 1980, only 3,073 (or 25.1 percent) were still receiving ICF-II services in December 1984. Another 1,249 "Special IIS" were also receiving ICF-II services as of that date. The institutional population decreased [illegible] percent from March 1980 to December 1984, from 69,063 to 56,613. The community care caseload has increased 46.2 percent, from an average of 35,2[illegible] cases in 1980 to [illegible] in 1984.

New York, Monroe County [illegible]

The New York State Department of Social Services is demonstrating alternative approaches to delivering and financing long-term care to the adult disabled and elderly Medicaid population of the county. The project has developed the Assessment for Community Care Services (ACCESS) project as a centralized unit responsible for all long-term care services for Monroe County residents 18 years of age or older who are Medicaid eligible and have long term health care needs. ACCESS staff provide [illegible] assessment and case management services. The Monroe County Long Term Care Project was expanded in 1982 to [illegible] assessment services for the county's Medicare population in need of long term care. The addition of the Medicare waiver [illegible] for the project to work toward an integration of Medicare and Medicaid long term care strategies in the county and [illegible]. The project operated at full capacity through [illegible] 198[illegible]. The demonstration has been extended until 1986 to assess the [illegible] effect [illegible] long term care system.

Home Health Agency Prospective Payment Demonstration

A contract was awarded in September 1983 to Abt Associates, Inc. for the development and implementation of a demonstration testing alternative methods of paying home health agencies (HHAs) on a prospective basis for services furnished under the Medicare and Medicaid programs. The initial phase of the project will involve the development of the specific payment methodologies (e.g., per visit, per month, per episode), establishment of a research design and evaluation strategy, design of a process to monitor the quality of care provided under the demonstration, development of data collection and reporting systems, and identification, selection and training of participating HHAs. The payment methodologies will then be tested for three years to determine the effects on Medicare and Medicaid expenditures, quality of care, and HHA operations. This operational phase is expected to begin [illegible].

Development of Home Health Agency Competitive Bidding Models

A contract was awarded in June 1984 to the Center for Health Policy Studies, Inc. to design alternative models of competitive bidding for home health agency services under the Medicare and Medicaid programs. The contractor will be required to analyze strengths and weaknesses of possible models, including possible effects on access to and availability of services, and on Medicare and Medicaid expenditures. The contractor will develop in detail several models selected by HCFA and establish a research design and implementation strategy that could be used by HCFA to test the bidding models in a demonstration project. The contract will be completed in early 1986.

South Carolina Community Long Term Care Project

The South Carolina Department of Social Services was awarded a section 1115 grant in September 1979 to conduct a demonstration to test community-based client assessment, services coordination, and provision of alternative services. In September 1981, the project received section 222 waivers to address the needs of project clients who are eligible for both Title XVIII and Title XIX benefits. It was hypothesized that the waivers would increase the use of home care services and, thereby, reduce reliance on hospitals and lower the incidence of conversion from Medicare to Medicaid in nursing homes. The project's catchment area covered three counties: Spartanburg, Cherokee, and Union.

The demonstration ended in December 1984. All appropriate clients were transferred to the statewide community long term care system under the authority of the section 2176 waivers. The State submitted to HCFA a draft final report in the fall 1985. A final report and an executive summary are expected to be submitted to HCFA in early 1986.

Study of Accidental Falls in the Elderly

In September 1984, a cooperative agreement was awarded to the Kaiser Foundation Research Institute to test the effectiveness of a comprehensive falls prevention program in reducing the incidence of falls and associated medical care use and cost in the elderly population. The project will be conducted at the Health Services Research Center, Kaiser Permanente Medical Care Program in Portland, Oregon. Kaiser will be conducting a randomized trial of 2,400 households with Kaiser members age 65 and over who will participate in one of two groups: intervention and a control group. All participants will provide data on falls and will receive a home audit. Participants in the intervention group will be offered a special falls prevention program which will include a self-management educational curriculum and the installation of safety equipment and minor renovations in the home. In addition, a blind control group of elderly Kaiser members will be included to measure the incidence of falls-related medical care use. The project will collect data for a 24-month period on all participants. Funding support for this demonstration will be supplemented by the National Institute on Aging, the Robert Wood Johnson Foundation, and Kaiser Foundation Hospitals, Inc. The project completed its planning and development activities and began recruiting clients in September 1985.

Connecticut Incentive Reimbursement Plan for Medicaid Home Health Care Services

In November 1984, the State of Connecticut received a 2-year award to conduct a demonstration project which will investigate the degree to which the payment of cash rebates to Medicaid recipients who use low cost home health agencies will be effective in lowering overall Medicaid home health care costs. The project will include 1,250 Medicaid recipients in Hartford, Connecticut. Project Hope's Center for Health Information Research and Analysis in Millwood, Virginia will be the evaluator of the demonstration.

Prior to implementation of the full-scale demonstration project, however, the State intends to conduct a 6-month pilot project. Because of some unexpected delays encountered in the planning phase of the project, the pilot project will not begin until the latter part of 1985, with the full-scale demonstration beginning early in 1986.

The Social/Health Maintenance Organization Demonstration

[illegible]

[illegible]

[illegible]

[illegible]

the Ebenezer Society/Group Health Plan of Minneapolis, Minnesota (Seniors Plus) are Health Maintenance Organizations which are adding long term care services to their service package. Elderplan Inc., sponsored by the Metropolitan Jewish Geriatric Center in Brooklyn, New York, and the Senior Citizen Action Network (SCAN) of Long Beach, California are long term care providers which will be adding medical services to their packages.

One site, Seniors Plus, became operational on January 1, 1985. The other three sites commenced operations on March 1, 1985. During the 18-month first year, the sites will attempt to reach an enrollment level of 4,000 participants per site.

An evaluation contract was awarded to the University of California, San Francisco (UCSF). The evaluation is designed to provide answers to questions about cost/benefit effects of a S/HMO, the effects of integrated care on the elderly and on service costs, the administrative feasibility of the S/HMO model compared with the fee-for-service model, and the effects on quality of care.

In addition to the UCSF evaluation, HHS and each site will conduct an evaluation of the process of developing and implementing a S/HMO program.

Incentive Payments for California Nursing Homes

The California Skilled Nursing Incentive Payment Project is designed to test a system of incentive payments as a means of encouraging skilled nursing facilities (SNFs) in San Diego to admit and provide quality care to severely dependent patients now being backed up in hospitals because of the amount and cost of care these patients require. Effective April 19, 1980, HCFA approved waivers of certain statutory requirements for this project so that the California Medicaid State Agency might set nursing home payment rates which exceed the Medicaid reasonable cost requirements by the amount of the incentive payments. The total funding for this project is paid through a contract between the National Center for Health Services Research (NCHSR) and its contractor, Applied Management Sciences, Inc. (AMS).

Under the demonstration, AMS randomly assigned 36 SNFs to the treatment and control groups. Based on periodic patient assessments by specially trained nurses, the 18 treatment group SNFs received admission, discharge, and outcome incentive payments (for achieving patient-specific outcome goals). The operational phase of the project lasted from May 1981 through April 1983. Currently, project staff at NCHSR and AMS are editing the study data and laying the groundwork for the analyses. The final evaluation report is scheduled for completion in early 1986.

HUD/HHS Demonstration for the Chronically Mentally Ill

This demonstration project is a joint effort between the Department of Health and Human Services (HHS) and the Department of Housing and Urban Development (HUD) to allow the chronically mentally ill to live more independently in the community through the provision of residential housing and services. Project coordination is carried out by an interagency work group from HUD and HHS, Health Care Financing Administration (HCFA), National Institutes of Mental Health (NIMH), and the Office of the Assistant Secretary for Planning and Evaluation.

The current demonstration began in 1978 with HUD approving section 202 Direct Loan Reservations and Section 8 Rental Assistance set-asides for sites in 39 States and NIMH approving the service programs for each site. HCFA is committed to the provision of section 1115 Medicaid waivers to permit reimbursement for services not currently reimbursed under the States' Medicaid plans. Of the 39 HUD-approved States that initially indicated their interest in requesting a grant approval, 12 States (Massachusetts, Georgia, Tennessee, Vermont, the District of Columbia, New Hampshire, New Jersey, Rhode Island, Maryland, Washington, Connecticut and Maine) have submitted grant requests and received their Medicaid waiver-only grant approvals by HCFA. During the course of this demonstration, the waivers will cover reimbursement for services from three to a maximum of 3.5 years.

The objectives of this demonstration are (1) to determine the cost-effectiveness of providing care to chronically mentally ill in noninstitutional settings and to determine the outcome in functional dependence and quality of life of the residents.

Case Managed Medical Care for Nursing Home Patients

On July 1, 1983, HCFA approved Medicare and Medicaid waivers to the Massachusetts Department of Public Welfare, Medical Care Division, to permit fee-for-service reimbursement for the provision of medical services by physician-supervised nurse practitioners to residents of designated nursing homes. This will permit increased medical care access that will generate cost savings due to fewer hospital admissions and less utilization of inpatient services. For those requiring a hospital admission, the nurse practitioner will be the admitting physician, thus providing a continuity that is frequently lacking in the present system of medical care. Massachusetts has contracted with [illegible] nursing homes with medical services delivered by the Urban Medical Group. This program will be expanded to serve a patient population of approximately 700 patients. In addition, other medical groups will be added and approximately [illegible] patients are expected to be served by [illegible] at a cost of [illegible]. The objectives of the demonstration are to measure the feasibility and desirability of the use of nurse practitioners, physician assistants to provide medical care to residents of nursing homes and to test the cost-effectiveness of this delivery system.

On Lok's At-Risk, Capitated Payment Demonstration

As of November 1, 1983, in response to the Congressional mandate of Section 603(c)(1) and (2) of the Social Security Amendments of 1983, HCFA granted Medicare waivers to the On Lok Senior Health Services and Medicaid waivers to the California Department of Health Services. Together, these waivers will permit On Lok to implement an at-risk, capitated payment demonstration in which 300 frail elderly individuals are provided a comprehensive array of health and health-related services.

Under On Lok's Community Care Organization for Dependent Adults (CCODA) demonstration that began in 1979 and ended on October 31, 1983, a single source, cost-based, reimbursement system (Medicare) was used to provide funding for all health and health-related services to On Lok's CCODA participants who were certified by the Department of Health Services as eligible for institutional placement at the time of admission. Reimbursement for services was provided by HCFA under section 222 waivers.

The current demonstration is maintaining On Lok's comprehensive community-based program but has modified its financial base and reimbursement mechanism. All services are paid for by a prospective capitated rate from both Medicare and Medicaid (Medi-Cal). The Medicare rate is based on the adjusted average per capita cost (AAPCC) for Medicare's institutionalized population. Individual participants may be required to pay co-payments, spenddown income or divest their assets based on their financial status and eligibility for either or both of the programs. On Lok is at risk if expenditures exceed the capitated rates of both Medicare and Medi-Cal.

Respite Care Co-op for Impaired Elderly

This feasibility study is expected to develop a model cooperative to provide respite for family caregivers of impaired elderly. The model relies on volunteer family caregivers with a minimum number of paid staff to coordinate the process. The objectives are: to study the feasibility and cost of developing a model cooperative designed to prevent exhaustion of family members, to eliminate the need for more intensive and/or expensive care, and to prevent unnecessary institutionalization of the elderly. The model is envisioned as a cooperative committee composed of impaired elderly, their family caregivers and representatives from community agencies. The committee, with a program coordinator, works to establish policies and procedures and to recruit families to participate. Family members pay for care received with care given. The co-op model is professionally guided self-help and volunteerism, with the caregiver as both service provider and service recipient. The evaluation will provide data to measure satisfaction and impact on well-being of clients and caregivers, cost-effectiveness and avoidance of use of more costly and restrictive living circumstances.

The Effects of Alternative Family Support Strategies

This project is designed to study the effects of various support programs provided to families that care for their elderly members at home. The support programs include:

1) paid respite care coverage [illegible] monthly dollar limit per family,

2) family training and case management, and

3) paid respite care in conjunction with family training and case management.

The purpose of providing the support programs is to encourage and enable family members to maintain their role as primary caregivers in order to prevent or delay the permanent institutionalization of their elderly relatives.

The Long Term Care Center and the Institute of Aging of the University of Washington (Seattle, Washington) are co-sponsoring the project, which will be offered in the King County area. To take part in the project, a dependent family member must be: 1) age 65 or over and 2) entitled to Hospital Insurance (Medicare Part A) or eligible under the Medicaid program. Three providers will participate in the project to offer families a choice of paid respite care: Community Home Health Care, Norwest Day Health Center for Adults, and Northwest Progressive Care (a nursing home which offers both skilled and intermediate levels of inpatient care).

The design of this project calls for a total population sample of 600 family units (each consisting of an elderly dependent member and a family caregiver). The family units will be randomly assigned -- either to one of several experimental groups receiving one or a combination of the support programs (500 family units) or to the control group (100 family units). Families receiving paid respite care alone or the mix of paid respite plus training/case management services (200 family units) may use any combination of the paid respite care up to a maximum dollar limit per family (an annual limit of about $900). The service phase of the project began in April 1984 and continued through July 1986. The final evaluation report is expected in late spring 1988.

Nursing Home Survey Certification and Inspection of Care

There have been three States involved in Survey/Certification and Inspection of Care demonstrations. The Wisconsin Nursing Home Quality Assurance Project was completed in 1982. Under this experiment, the State performed a streamlined survey process that also met the requirements of medical and independent professional review in an attempt to improve the quality of nursing home care. The Massachusetts Survey and Inspection [illegible] developed and tested a method of conducting nursing home surveys so that the intensity of the regulatory effort was matched to the needs of particular facilities. The New York State Nursing Home Quality Assurance Program united the [illegible] of the federally mandated periodic medical review/independent professional review processes in nursing homes and combined the process with the annual facility survey. Surveyors used 11 sentinel health events (SHEs), such as [illegible], and medication regimens to determine if [illegible] patients were receiving adequate care. Facilities found to have fewer than the average number of [illegible] these areas received a less than full facility survey. This allowed survey personnel to focus on facilities and patients with major problems. The [illegible] indicates that the facility is taking more corrective actions than usual as a result of the new procedures but that fewer facilities are being cited for [illegible].

An evaluation of the Wisconsin project was completed by Wisconsin Health Care Review, Inc. Further evaluation of this project and the evaluation of the Massachusetts and New York projects have been conducted under a contract with Mathematica Policy Research, Inc. The evaluation will [illegible] data collection and [illegible] of all three projects. The evaluation will determine:

1) the reliability and validity of the new methods compared to the old ones;

2) the effectiveness of the new methods in [illegible] poor quality care; and

3) the actual and potential cost savings of the methods.

In addition, the contractor will compare and contrast the methods used in these three different projects to estimate how the quality assurance process can be improved to reduce costs and allow the States appropriate flexibility. The draft of the final report has been received and is being reviewed. The report was completed in late 1985.

In addition to these demonstrations, the Massachusetts Statistical Quality-Control Approach to Inspection of Care Project began in February 1983. The main objective of the project is to verify that patients in nursing homes are receiving appropriate care at the appropriate level, without reviewing every patient. Current law requires a review of all patients in a facility to verify the appropriateness of care and placement. This project will use statistical sampling techniques to achieve these goals so that surveyor time can be reallocated to other quality-assurance activities. Criteria have been developed for determining which facilities are appropriate for the sampling process. The procedures for sampling patients, including safeguards to control statistical biases, have been refined. The project became operational in August 1983 and will be completed in 1986. This project will have a separate evaluation.

New York State Case Mix Prospective Reimbursement System for Long Term Care

The New York State Department of Social Services was awarded a section 1115 grant, effective August 7, 1983, to develop, test and refine a Long Term Care prospective payment system based upon clusters of patient characteristics. This is a 3-year grant being conducted by the New York State Department of Health and Rensselaer Polytechnic Institute. The system will build upon the results of research conducted at Yale University which developed clusters of patients in relation to staff resources used (Resource Utilization Groups, RUGS). The purpose of the project is to promote efficiency by associating payment levels with patient characteristics which indicate the amount of actual services needed by patients.

The first step of the demonstration was to validate the RUGs by determining whether additional or different patient clusters are appropriate for New York. Data was collected on 4,000 patients and staff from 40 facilities stratified by level of care, ownership, region, size, current case mix intensity and a willingness to participate in the project. From these data, patient groups were developed using AUTOGRP (a clustering program). These patient clusters were compared to those derived at Yale, using Klastorin's techniques to demonstrate whether the same patients would be grouped in the same RUG under each system.

The second step was to analyze the nursing home resource consumption in relation to the new patient classification system. The analyses allocated total facility costs into those categories which are related to case mix and those which are not. Data from certified facility cost reports and other sources were used to calculate a dollar value per relative value unit for each RUG or case mix index value.

The third and final step in the development phase was be to translate the case mix and cost information into a payment system. The State prospective payment rate incorporates: case mix intensity, fixed cost of the group of services shared across all residents, and overhead expenses related to facility characteristics. This new payment system will be phased in for all nursing homes in New York State starting January 1, 1986.

Texas Long Term Care Case Mix Reimbursement Project

The Texas Department of Human Resources was awarded a section 1115 cooperative agreement effective September 30, 1984, to develop a prospective reimbursement method based on facility case mix. The reimbursement method will be designed to match reimbursement rates more closely to patient characteristics and service requirements than the present flat rate system. The project will build upon the methodologies developed in New York and other States. The purpose is to contain costs while restructuring financial incentives to allow Medicaid patients improved access and quality of care.

The first step will be development of the data collection methodology, including the revision of patient assessment instruments to collect patient characteristics and staff time comparable to New York's information. Data will be collected on 2,000 patients and staff from 50 facilities stratified by certification type, ownership, size, current case mix intensity and willingness to participate in the project. From these data, patient groups will be developed using several statistical methods for grouping patients including AUTOGRP and GOM. These patient groups will then be compared to those used in other classification systems.

The second step will be to analyze the nursing home resource consumption in relation to the patient grouping methods. Following this, selection of a classification and reimbursement system for demonstrations will be made and a demonstration project will be designed to compare cost containment, patient access and quality of care to the present system.

Inpatient Geriatric Research Continence Project

The Gerontology Research Center (GRC) of the National Institute on Aging (NIA) will conduct a demonstration to test whether providing bowel and bladder training to incontinent skilled nursing facility (SNF) patients can reduce the cost of caring for the patients. For the past several years, GRC has conducted a clinical study on ambulatory outpatients who suffer from bowel and/or bladder incontinence. The procedure used to assist these patients in achieving bowel or bladder control utilizes biofeedback and other behavioral modification techniques. The use of this training showed marked improvement in the majority of the patients in the study. Under joint funding from NIA and HCFA, GRC will test whether these and other training procedures will be as effective on an inpatient basis with SNF patients. The demonstration, which will run for 3 years, is expected to start training patients in December 1985.

Future Directions for Long Term Care Demonstrations

During 1985, HCFA devoted substantial staff resources on the further development of demonstrations to test the cost-effectiveness of a prospective payment system for nursing homes and home health agencies. Refinement of methodologies which take into account patient case mix in setting prospective rates for nursing home and specifying the elements of per visit, per diem, and per episode rate setting approaches for home health agencies were just some of the activities accomplished in this area during 1985.

We will continue to test alternative financing schemes for long term care services, including patient-related or case mix based prospective payment and competitive bidding systems for skilled nursing facility and intermediate care facility levels of care. We also intend to test the effectiveness of innovative State, local, and private programs to promote home care by the family or by other community support arrangements, e.g., projects which focus on long term care populations such as Alzheimer's patients, AIDS victims, and institutionalized elderly or persons at risk of institutional care because they have no family network and which provide in-home or other support services (adult day care, adult foster care or shared housing) to substitute for or deter the institutional care of such persons.

RESEARCH ACTIVITIES

Long term care research activities in the ORD can be classified according to five objectives: developing prospective payment systems for long term care; promoting alternatives to long term care; assessing and evaluating long term care programs; examining the effect of the hospital prospective payment system on long-term care providers; and supporting data development and analyses.

PROSPECTIVE PAYMENT

In the area of prospective payment, an Urban Institute study is analyzing alternative approaches to prospective payment for Medicare skilled nursing facilities (SNFs) and has investigated administrative factors that affect the efficiency of patient-related, rate-payment systems. Analysis of the Medicare cost reports of skilled nursing facilities has shown that several proxy measures of case mix are important factors in explaining differences in SNF per diem costs. Higher costs are associated with a greater percentage of Medicare days, a higher number of admissions per bed, and greater nursing hours per inpatient day. These factors may indicate facilities with a greater orientation towards the short-term, rehabilitative Medicare patient. This project provided much of the technical analysis contained in the report "Study of the Skilled Nursing Facility Benefit Under Medicare," that was submitted to the Congress in January 1985.

Other studies related to prospective payment include analyses of case mix differences and their incorporation into payment systems and analyses of State Medicaid payment systems.

Case-Mix Studies

The escalation of nursing home expenditures and the demand for services make it essential that methods be developed which ensure that long term care resources, which will become increasingly scarce, be properly matched with those most in need. The current payment system has been criticized for failing to differentiate according to the resources consumed by each nursing home resident, e.g., payment is the same for patients having less intensive needs compared to patients with "heavy care" requirements. This has resulted in problems of access to care for the latter group of patients. In order to solve this problem, appropriate systems to quantify the long term care needs of the elderly patient are required.

A variety of methods, including case-mix, have been designed which evaluate resource consumption of nursing home patients with the goal of developing more appropriate payment systems. A University of Colorado study has provided case-mix comparisons of Medicare and other nursing home patients and comparisons of patients in hospital-based and freestanding nursing facilities. Detailed results are presented in a report entitled, "Nursing Home Case-Mix Differences for Medicare Versus Non-Medicare and Hospital-Based Versus Freestanding Patients."

In its final year, the project will assess the cost effectiveness of nursing home and home health care for patients with the following problems: stroke, decubitus ulcers, congestive heart failure, urinary incontinence, and mental problems. Emphasis is being placed on comparing outcomes for these patients over time in hospital-based and freestanding nursing home care and those in nursing homes versus home health care. A report on this analysis is expected early in 1986.

A Yale University project is refining their earlier work on the correlation between long-term patient characteristics and the resources required for their care. The purpose of this research is ultimately to refine resource utilization groups (RUGs) and design a case-mix system which could provide a basis for differential payments to nursing homes based on the intensity of services consumed by groups of patients with similar care needs. These payments potentially could include nursing costs and costs of rehabilitative services, such as physical and occupational therapy. This project is attempting to correct some deficiencies in the original RUGs, e.g., the inclusion of some process variables, instead of just clinical variables, and reliance on subjective estimates of staff time. Unlike the prior project, it will take into account the rate at which patients' conditions change, and will develop RUGs for the rehabilitation services. A five-group RUGs model has been developed and is being revised and validated. The final report for this project is due in March 1986.

Using a data base that contains information on the characteristics and resource consumption of 1,800 Medicare patients, researchers at Rennselaer Polytechnic Institute plan to develop a patient classification system for Medicare SNF patients. The role of diagnostic variables and service/treatment variables as part of the classification system will be evaluated. This project will also begin work developing relative case mix weights for each classification and methods for HCFA to use in computing total weights for all resources within long-term care facilities. Lastly, the Medicare classification system will be compared to the case mix system developed for long-term care in New York State (this project is discussed in the section on demonstrations). Data collection for this project has been completed and development of the Medicare RUGs is underway. Initial findings indicate that the Medicare RUGs will differ considerably from those developed for Medicaid patients in the New York project. The final report for this project is due early in 1986.

Medicaid Payment Studies

Several states are currently using different methods of nursing home payment for Medicaid patients, some of which incorporate case-mix. Studies are underway which are evaluating the design and implementation of these systems and their effectiveness in achieving the goals of containing costs, maintaining or improving quality and ensuring access.

The University of Colorado has a 4-year grant to compare long term care payment systems in seven States. West Virginia, Ohio and Maryland will be used as examples of case mix States. Florida and Colorado will be studied as States with facility-specific prospective systems that do not incorporate case mix directly but still treat direct patient care costs separately from other cost centers. Texas and Utah will be used as States that utilize class rates for either the entire payment rate or the non-capital rate components. Data sources for this study include primary data gathered from the facilities and from patient samples, as well as secondary sources such as cost reports. Results are expected in 1988.

The University of Southern Maine is studying the recently implemented nursing home prospective payment system in Maine. The study will conduct a 3 year pre-prospective payment and 3 year post-prospective payment impact analysis on cost, quality and access. Results are expected in early 1987.

PROMOTING ALTERNATIVES IN LONG TERM CARE

Research activities in this area can be classified into two major divisions: community-based alternatives to institutional care; and alternatives to current financing mechanisms of long term care.

Community-Based Alternatives

While nursing home care is appropriate for a small subset of the elderly population, evidence indicates that a substantial proportion of those who have been institutionalized could have continued to reside in the community with adequate support. Most aged persons with functional limitations prefer to remain in the community as long as possible. Noninstitutional approaches are being developed with the objectives of avoiding or delaying unnecessary institutionalization, maximizing the independence and well being of the elderly, and providing care in the most cost-effective manner.

Current studies focusing on community-based alternatives to institutional care include such issues as family caregiving, utilization of home health services, determinants of public and private contribution in long term care provision.

A study by Abbott Northwestern Hospital is replicating the methodology used in another HCFA funded study (Hunter College, 1982) to examine the family caregiving system of the elderly in Minnesota. Unlike the Hunter College project, the sample for this study will be drawn from hospital patients rather than from clients of home health and other community based agencies. It will also include rural as well as urban residents. Detailed data has been collected on the caregiving experiences of families of disabled elderly which will permit this project to assess the impact of formal support systems, such as health and social services, on the provision of home care. In the past year this study was expanded to include a nursing home sub-study in which data will be gathered on 150 hospital patients who are discharged to nursing homes and their caregivers. Results are expected in late 1986. The data for this project have been gathered and preliminary data analyses are underway. A final report is expected in early 1987.

The Community Service Society examined the effects of provision of home services programs to functionally disabled adults in New York City. The final report was received in July 1985. This study found that nearly half of the most disabled study subjects who were living alone did not have formal home services in place at hospital discharge. The report recommends stronger discharge planning in hospitals. It also identified a need for improved respite care services for informal supports who live with the care recipients and provide extensive help. The findings indicated that, of those needing help with various Activities of Daily Living and Instrumental Activities of Daily Living tasks, over 90 percent reported receiving some help with all but three tasks (going outside, traveling short distances, and heavy housework). Subjects receiving formal services tended to report high levels of satisfaction with the care they received.

The University of Maryland is examining determinants of public and private contributions to long term care of the elderly who are disabled by hip fractures. The impact of family size and composition, social support, family economic resources, and the aged individual's physical and mental health will be analyzed in terms of the decision to enter a nursing home or return home. The results are expected in late 1986.

Alternative Financing Mechanisms

With the rapid escalation of public expenditures for long term care and the projected growth in the elderly population, many different alternatives to current financing mechanisms are being investigated. Two studies have recently begun which are examining the potential for increased family support, either through tax incentives or cost sharing under family responsibility laws. The market for long term care insurance is also being assessed. Another area being examined is the use of life care centers as a private financing mechanism for long-term care services. HCFA's interest is whether Medicare and Medicaid service use and costs are lower for life care residents than for comparable community residents.

In the first study, the Center for Health and Social Services Research is evaluating four state tax incentive programs (Idaho, Iowa, Arizona, and Oregon). The purpose of this project is to study selected State tax incentives that are believed to stimulate the informal caregiver system and reduce either current or anticipated demands on the formal long-term care system. Specific objectives are: (1) to describe and analyze tax incentives that have been implemented in selected States; (2) to develop a predictive model to identify those persons in the general elderly population and their informal caregivers who are likely to take advantage of tax incentives; and (3) to determine the potential impact of the tax incentive programs in preventing or delaying institutionalization. Results are expected by the end of 1986.

The second study by the Hebrew Rehabilitation Center for the Aged is studying the potential of alternate payment schemes for long term care by children of elderly. The research will: (1) provide an estimate of chldren's resources available to share in the costs of long term care; (2) assess the attitudes of those children towards family responsibility proposals for sharing long term care costs; and (3) assess the market for long term care insurance. Results are expected in late-1985.

The ORD has provided support to two projects examining various aspects of long-term care insurance. The first project, sponsored by SRI International, is reviewing and analyzing models for private sector financing of long-term care, focusing on methods that Federal and State governments and the private sector might use to encourage new approaches. The project will identify actions that Federal and State Governments and the insurance industry can pursue to encourage the development of the market for different forms of long-term care insurance. The project report will be issued in December 1985.

The second project is the National Association of Insurance Commissioners (NAIC) task force on long-term care insurance. This effort will consider such issues as: (1) appropriate policy design and pricing; (2) existing statutory and regulatory barriers to development of this market; (3) desirability of legal changes, including tax incentives for fostering growth; and (4) need for, and design of, educational efforts to understand long-term care coverge and risks. ORD and HCFA's Office of Legislation and Policy have provided support by describing the needs for actuarial data for development of long-term care insurance policies and by developing an inventory of what data is actually available. The NAIC task force report is expected in June 1986.

In the life care area, Duke University is conducting a study which will compare life care residents with community residents over time with respect to functional status and health service utilization and costs. The study will analyze existing longitudinal data collected from a life-care facility in North Carolina and from the General Accounting Office survey of elderly people in Cleveland, Ohio. Study results are expected in early 1986.

The Hebrew Rehabilitation Center for the Aged has begun an evaluation of life care communities. Major issues which this study will address are: (1) the types of elderly that enter life care communities; (2) the costs of services within the various types of life care communities and their comparison with costs of services within the community; (3) the differences in the use of formal health care-services between elderly residents of life care communities and a similar population living in the community; and (4) the comparison of life satisfaction and longevity among the elderly in life care communities and among community-based elderly.

Data will be gathered from 20 life care communities in four States (Arizona, California, Florida, and Pennsylvania). Three types of life care community residents will be sampled: new admissions, existing tenants and tenants who died just prior to the data collection period. For all but the termination sample (where there is a separate questionnaire), quality of life and service utilization data will be gathered for two points in time. Three types of comparison samples of elderly living in the community will be used. Results are expected in early 1987.

PROGRAM ASSESSMENT STUDIES

Medicare Studies

Another group of research studies investigate specific aspects of Medicare long-term care policies. For example, as requested by Section 904C of the Omnibus Budget Reconciliation Act (OBRA) of 1980, the University of Colorado is conducting the evaluation of the "swing-bed" program under Medicare and Medicaid. The swing-bed option is open to hospitals with fewer than 50 beds located in rural areas with a shortage of long-term care resources. Among the issues to be examined in this evaluation are: the effect of such programs on availability and effective and economical provision of long term care services; whether such programs should be continued and whether eligibility to participate in the program should be extended to other hospitals, regardless of bed size or geographic location, where there is a shortage of long term care beds. Results are expected in mid 1986.

ORD is continuing work on three studies concerning coverage and reimbursement of home health services. Two studies, mandated by Public Law 96-499, the Omnibus Reconciliation Act of 1980, assess Medicare home health coverage for respiratory therapy and registered dietitian services. The third study, mandated by Public Law 97-414, analyzes current and alternative payment methodologies for home health services. All three studies are to be submitted to Congress during 1986.

In October 1982, Congress expanded the Medicare benefit structure to include hospice care and created a new type of provider - hospices. The hospice benefit was wuthorized only to October 1986. HCFA is evaluating the program experiences with the hospice benefit. Studies are addressing the issues of whether the coverage provisions of the benefit and the reimbursement metods are fair and equitable and promote the most efficient use of hospice care. The evaluation will analyze hospice costs, Medicare expenditures for hospice services, and the impact on the use and expenditures for other Medicare-covered benefits. An initial Report to Congress prepared by the Bureau of Eligibility, Reimbursement and Coverage is due January 1986; a more comprehensive report to be prepared by ORD is scheduled for January 1987.

Medicaid and Other Public Programs

In recent years, a number of different programs have been initiated by State and Federal Governments to improve the delivery and financing of long term care services. There are several projects underway to assess such programs.

The University of California at San Francisco will examine the effects of State Medicaid discretionary policy actions since 1981 and their effects on program utilization and expenditures for the nursing home market. It is a follow-on to a study previously funded by HCFA. The new study will update the existing data base and focus on both the aged and the disabled Medicaid populations who use these facilities. Results are expected in late 1987.

Another program assessment study involves the mentally retarded and developmentally disabled (MR/DD). The intermediate care facilities for the mentally retarded (ICF/MR) is one of the fastest growing benefits in the Medicaid program. The University of Minnesota is updating the only national information system on long term care services for the mentally retarded and developmentally disabled. National surveys of residential facilities and State statistical offices have been conducted to monitor deinstitutionalization trends. The draft final report from this project has been received. Findings indicate that States vary remarkably in the total size and characteristics of their ICF/MR programs, in the proportion of their residential care systems certified for the ICF/MR program, and in the growth/reduction of their ICF/MR programs between 1977 and 1982. ICF/MR expenditures (both Federal and State) were the fastest growing component of both State residential care and Medicaid long-term care expenditures. Early increases in ICF/MR expenditures (pre-1977) were due more to increases in total recipients of care than to increases in per recipient costs. Later increases have been due primarily to increases in per recipinet costs. About 70 percent of the increase in program costs from 1977 to 1982 can be attributed to increasing per diem costs. Other findings were that the ICF/MR population is more severly impaired than it was in earlier years and that there is a continuing trend toward less institutional models of care.

In 1983, HCFA's Office of Research and Demonstrations began a 3-year project to assess the changes made in the Medicaid program as a result of recent legislation. The Medicaid Program evaluation will focus principally on program changes since the Omnibus Budget Reconciliation Act (OBRA) of 1981, an Act which considerably increased State flexibility in determining eligibility, reimbursement, and coverage under the program.

Issues for study were selected by interviewing over 40 Medicaid policy-makers regarding evaluation needs. The key components of the evaluation are:

a. Home and Community Based Waiver Program. Under Section 2176 of OBRA 1981, States under a waiver may institute a variety of home and community based services to individuals who "but for" the waiver would be in long-term care institutions. The major questions are: (1) Has the program reduced institutionalization? (2) Has the program reduced costs? (3) Has there been cost shifting from other programs, specifically Title XX of the Social Security Act and Title III of the Older Americans Act? (4) Can we identify the elements of a successful program? This phase of the evaluation is being conducted by LaJolla Management, Inc. A Report to Congress on preliminary results of the evaluation was completed in 1985.

b. Financial Incentives for Family Care. Several States provide financial support through direct payments or tax incentives to family members to help them to care for their elderly relatives in the home. The major questions are: (1) What programs are in operation? (2) What have been their costs and savings? (3) Who are the beneficiaries of such programs, and what are their characteristics? (4) What are the characteristics of functionally limited persons living in the community which permit them to avoid institutionalization? (5) What are the characteristics of successful programs? Systemetrics, Inc. and LaJolla Management, Inc. are conducting this part of the evaluation.

c. Inpatient Hospital Reimbursement. To help bring hospital costs under control, OBRA 1981 granted the States new flexibility in the establishment of inpatient hospital reimbursement methods. Major questions are: (1) What responses have States made to the options permitted by Federal law? (2) Have reductions in expenditures resulted? (3) Specifically, what has been the impact of the California program? Two other State programs will be studied for comparison. (4) What have been the effects on recipients and providers of care? (5) Have costs been shifted to private payors? (6) To what degree and in what ways has the implementation of Medicare prospective reimbursement impacted State Medicaid programs? Abt Associates is conducting this part of the evaluation.

d. Freedom of Choice Waivers. Under Section 2175 of OBRA 1981, States may institute a variety of programs (with and without waivers) to reduce costs by limiting the provision under Medicaid which guarantees freedom of choice of provider. Major questions are: (1) How have the States responded to this provision? (2) Have there been program savings? (3) How have access to and quality of health care been affected?

e. Eligibility. OBRA 1981 contained several changes which directly and indirectly reduced the number of persons eligible for Medicaid. The major questions are: (1) How have the States responded to these provisions? (2) How have eligibility changes in related program (AFDC and SSI) affected Medicaid enrollment? (3) How have entitlement and expenditures been affected? (4) How has the reduction in Medicaid coverage affected other assistance programs, out of pocket expenditures, and costs to hospitals and other payors?

f. Cost-Sharing. Under TEFRA 1982, States are permitted to impose nominal copayments, with certain limitations, to reduce program outlays and to instill cost-consciousness on the part of the recipients. Major questions that arise are: (1) How have the States responded and (2) What has been the effect of copayments on utilization and costs?

g. Federal Financial Participation. OBRA 1981 provides for the reduction of Federal matching funding for 3 years, beginning October 1, 1982, subject to certain exemptions. The major questions are: (1) Which States were exempted from the reductions and for what reasons? (2) How much did the Federal Government save? (3) How did the States adjust to reduced funding?

h. Subsequent Legislation. The principal legislative change since OBRA has been Medicare prospective payment. Impacts on Medicaid will be addressed.

i. Synthesis. A final task of the evaluation will be an interpretive synthesis of the study results.

Evaluation components d. through h. are being conducted by James Bell and Associates. The project will produce interim and final reports on all studies. The completed Report is expected to be available at the end of 1986.

Expansion of the Role of Nurse Practitioners

HCFA is also investigating the expanded role of nurses in the long term care area. A study by the Rand Corporation is evaluating the potential of the use of geriatric nurse practitioners (GNP) for improving outcomes of care and containing costs in skilled nursing facilities. Rand is assessing this potential by evaluating the effects of the Mountain States Health Corporation's GNP demonstration project. Thirty nursing homes that have a GNP are being compared with 30 nursing homes that did not have one on four points patient outcomes, process of care, nursing home costs, and history of certification deficiencies. Results of this study will be available in late 1986.

IMPACT OF HOSPITAL PROSPECTIVE PAYMENT ON THE LONG TERM CARE SYSTEM

The hospital prospective payment system (PPS), based on fixed payments for diagnosis-related groups, provides incentives to limit costs for each Medicare patient by controlling the amount of servies provided or limiting the hospital length of stay or both. Such incentives can potentially affect the long-term care system in several ways. Hospitals may respond by shifting care to settings outside the hospital. This shift to other settings may be appropriate for those with less intense service requirements and may result in cost savings for the health system. However, it is also possible that patients may be prematurely discharged from the hospital and the alternative settings may not be able to serve these patients' needs adequately. There may not be overall cost savings because of a greater number of patients being discharged to long-term care settings and more intensive services being required. Several studies have begun which examine effects of the hospital PPS on long-term care providers.

The purpose of a study being conducted by Georgetown University is to (1) determine how much the hospital PPS shifts care from the hospital to skilled nursing facilities (SNFs) and to home health providers; and (2) analyze the impact of this shift on total costs to Medicare and on changes in SNF characteristics that are likely to increase use by Medicare beneficiaries in the future. Medicare claims will be analyzed to determine how PPS has affected total service use (hospital, SNF, and home health) and costs for hospitalized patients. In addition, SNFs will be surveyed to identify changes in nursing home patients, services and market structure likely to affect Medicare use. The survey will be supplemented with data from the Medicare Medicaid Automated Certification System, SNF cost reports and other sources. Results are expected in early 1988.

In June 1985, the scope of the evaluation of the swing-bed program being conducted by the University of Colorado was expanded to include an assessment of the impact of the hospital prospective payment system (PPS) on the program. The swing-bed concept directly affects the continuum of care decisions at the hospital/skilled nursing facility interface. It is at that point where the effects of PPS are most likely felt. Expanding the scope of the original evaluation will provide a focused analysis of the effects of PPS at this point of impact. Since the institution of PPS, there has been a rapid growth in the number of hospitals offering swing-bed services. The report on this aspect of the evaluation is expected in November 1987.

Another study by the University of Colorado will collect case mix data during 1986 to permit an analysis of changes in nursing home and home health case mix since the introduction of the Medicare prospective payment system for hospitals in 1983. In 1983, the University of Colorado sampled 600 patients in high-volume Medicare skilled nursing facilities in five States (California, Pennsylvania, Ohio, Michigan, and Texas), and 600 non-Medicare patients in hospital-based and freestanding nursing homes in 10 States (Arkansas, California, New York, Michigan, Minnesota, Colorado, Florida, Virginia, Pennsylvania, and Ohio). The 1983 data will serve as baseline case mix information for comparison with the 1986 data. The study results are expected in early 1987.

DATA DEVELOPMENT AND ANALYSIS

In the past, information on the health status and health care utilization of the long term care population has been drawn almost exclusively from cross-section surveys, such as the National Nursing Home Survey. While useful, cross-section data have limitations. Two longitudinal survey efforts will provide a better picture of the transitions of disabled elderly living in households and of institutionalized patients.

Longitudinal Surveys and Analyses

The Long Term Care Survey interviewed 6,000 disabled elderly living in households in 1982 to determine the extent of their dependencies, utilization of both informal and formal services, and their income and assets. Descriptive reports will be produced beginning in the Spring of 1984. Currently planned are reports on demographic characteristics, ADLs and IADLs, formal and informal supports services, and income and assets. A paper giving a descriptive profile of the aged functionally impaired persons in the community in 1982 is planned for the Spring 1986 issue of the Health Care Financing Review. In 1984, these same persons were resurveyed to determine how they have fared since 1982. The resurvey will enable us to identify the most important factors that enable persons to remain in the home. In addition, those persons who were in institutions as well as persons who were not previously disabled will be included. This entire sample should provide a total picture of the functionally impaired elderly.

A survey of persons using long-term care facilities, particularly nursing homes, facilities for the mentally retarded, and psychiatric hospitals, will be a key part of the Institutionalized Persons Components of the 1987 National Medical Expenditure Survey (NMES). This survey will obtain data on the use of health care services in 1987 by persons who were resident in long-term care facilities on January 1, 1987 and those who are subsequently admitted to these facilities. The data on the use of and expenditures by these persons for health care services in 1987 will include those used prior to, during, and subsequent to their residence in a long-term care facility. This survey will provide the most comprehensive data on the use of and expenditures for health care services of persons requiring long-term care.

Longitudinal analysis and projections are also being conducted under a grant to Duke University. The grantee has developed state-of-the-art statistical methods for using mortality data to estimate and project the incidence of specific chronic diseases (e.g., cancer). The grantee will use HCFA-sponsored survey data, including the Long Term Care Survey, to forecast future changes in health status of the aged population and service needs.

A Harvard University project which was funded in July 1984 collected the fourth series of self-reported information from the Massachusetts Health Care Panel Study cohort. The cohort consists of persons who were in 1974 selected in a statewide probability sample of persons 65 years of age or older. Harvard is analyzing the data from each series of interviews to determine indications of functional decline prior to death, predictors of long-term institutionalization, and interrelationships among physical, behavioral, and social characteristics and subsequent health care and social services use and mortality.

Other HCFA Data Activities

Certain information concerning long term care services is routinely abstracted from the Medicare claims payment system and reported by HCFA. These are long stay hospitals, skilled nursing facilities, and home health services. Data relate primarily to length of covered stay, amount reimbursed for services, and types of facilities. Trend data is routinely available for these items.

HCFA is continuing work to enhance national Medicaid statistics by obtaining person-level data from state Medicaid Management Information Systems (MMIS). Major project goals include the development of uniform data sets among participating states; production of standard reports describing enrollment, use and expenditures under Medicaid; and support for special studies that focus on important policy, program management or other research issues for Medicaid. HCFA has obtained MMIS data from five states: California, Georgia, Michigan, New York, and Tennessee for the years 1980 through 1982 and is requesting data for 1983 and 1984. Data are extracted for enrollees, providers and claims for all types of Medicaid services, including long term care. In general, these data will be used to analyze expenditures and utilization of long term care services and to study the total care provided to institutionalized individuals under Medicaid. Several analyses are underway to study the older aged population (85 years and older), multi-State analysis of expenditures and utilization of long-term care by the aged, transitions from inpatient hospital to long-term care, and aged persons with hip fractures.

OFFICE OF HUMAN DEVELOPMENT SERVICES

Administration on Aging

The Administration on Aging's (AoA) Family and Community Based Care efforts stem from a concern that chronically ill and functionally impaired older persons have access to appropriate community-based care in order to prevent premature or unnecessary institutionalization. AoA recognizes one of its most important priorities to be assisting families in their efforts to care for older relatives, particularly those in the greatest social and economic need. AoA will assist States and other public and private organizations to develop community service systems that provide cost efficient and humane alteratives to long-term care in institutions.

- Title III - Older Americans Act (OAA): In order to address these priorities, AoA has identified three directions toward which it will encourage Area Agencies on Aging (AAA) to direct their resources to facilitate the development and provision of family and community-based care service delivery systems, particularly for those vulnerable elderly most likely to lose their independence. Although AAAs are now charged with these responsibilities under the OAA, AoA will more actively encourage AAAs to initiate and/or expand their current efforts in the three following priority directions:

  -- to increase their visibility and to serve as the focal point for aging matters within their own communities through greater public awareness;

  -- to serve as a catalyst in developing a comprehensive and coordinated system of services for the elderly in their communities through promoting the development of partnerships and systems changes, designed to improve the lives of older Americans; and,

  -- to improve the targeting of services both to those elderly in greatest need (the economically needy, especially minorities, and the frail elderly) and to families and persons caring for older relatives and friends.

- AoA/HCFA/ASPE Channeling Demonstrations: AoA collaborated jointly with the Health Care Financing Administration and the Office of the Assistant Secretary for Planning and Evaluation in a major initiative, the "National Long-Term Care Channeling Demonstration Program." "Channeling" refers to a set of community level functions and organizational structures that encompass case finding, comprehensive client assessment, case management, monitoring, and reassessment. Ten demonstration projects under State auspices were funded, several directly involving State and Area Agencies on Aging.

  The major purpose of this national effort was to provide the Federal government with information on a number of policy issues relevant to community-based long-term care for functionally impaired older persons. The evaluation component, the core of the demonstration, collected and analyzed data on such issues as channeling's impact on service utilization, cost-effectiveness, client outcomes and informal caregiving. Data was also gathered about the cost, implementation, administration and management of the channeling intervention itself. The evaluation contractor has submitted a number of different reports on the outcomes of the demonstrations throughout the autumn of 1985 and it is anticipated that the final report will be submitted in late spring of 1986.

- Long Term Care Gerontology Centers: In recent years Title IV - Older Americans Act support for 11 gerontology centers has been as follows:

FY 1983	$4.6 million
FY 1984	2.7 million
FY 1985	4.5 million
FY 1986 as enacted	.9 million
FY 1986 after sequestering	.9 million
FY 1986 revised	.9 million

The objective of this effort has been to develop centers that represent a collaborative effort between the Federal government and educational institutions to assist States and communities to improve the planning, management, and delivery of health and social services for chronically ill and functionally impaired older persons. The effort is intended to produce knowledge about the long-term care needs of older people and develop a cadre of professionals from a multiplicity of disciplines who can meet these needs.

Long-Term Care Gerontology Centers were funded from 1979 to 1986 to carry out the following programmatic activities: development and evaluation of models of continuum of care; development through career, and continuing education and training of professional and paraprofessional staff for the delivery of health care, personal care services; development of policy, and applied and clinical research to improve conditions for functionally impaired older persons; and information dissemination and technical assistance to State and local public and private agencies.

Begun in Fiscal Year 1979, the program has encompassed 11 Centers covering all of the nation's geographic regions. AoA has emphasized the development of linkages between the Centers and State and Area Agencies on Aging so that the Aging Network can benefit immediately from the knowledge, information and personnel generated by the Centers. The Centers have also joined together to develop an information system consisting of data about their organizational and programmatic activities. The system will provide an important source of information for AoA and State and Area Agencies about the Centers' work and outcomes that may be applicable to other geographic areas.

MATERNAL AND CHILD HEALTH

Obligations

	1983 Actual	1984 Actual	1985 Actual	1986 Appropration	1986 After Seqestering	1986 Revised Estimate	1987 Estimate
Public Health Service:							
Health Resources and Services Administration:							
Bureau of Health Care Delivery and Assistance...	478,000	399,000	478,000	478,000	457,446	457,446	478,000
Bureau of Health Professions...............	9,168,171	8,803,425	7,970,440	7,989,194	7,634,259	922,418	—
Total, HRSA.........	9,646,171	9,202,425	8,448,440	8,467,194	8,091,705	1,379,864	478,000
Center for Disease Control:							
Immunization...............	39,253,000	42,068,000	54,142,000	59,594,000	57,032,000	57,032,000	56,012,000
Lead Base Poison...........	533,000	533,000	533,000	533,000	510,000	510,000	533,000
Total, CDC...........	39,786,000	42,601,000	54,675,000	60,127,000	57,542,000	57,542,000	56,545.000
National Institutes of Health							
National Institute of Child Health and Human Development.........	152,346,000	169,460,000	197,875,000	203,680,000	194,512,000	193,812,000	195,255,000
National Cancer Institute..	32,067,000	39,280,000	55,368,000	62,400,000	58,800,000	58,600,000	56,700,000
National Heart, Lung & Blood Institute.................	25,470,000	27,554,000	38,724,000	41,425,000	39,600,000	39,000,000	37,850,000
National Institute of Dental Research...........	6,666,000	6,528,000	12,627,000	13,307,000	12,735,000	12,735,000	12,098,000
National Institute of Arthritis, & Musculoskeletal & Skin Disease...	5,830,000	6,580,000	7,950,000	8,400,000	8,000,000	7,900,000	7,700,000
National Institute of Diabetes, and Digestive and Kidney Disease........	30,236,000	33,780,000	39,300,000	42,400,000	40,300,000	39,600,000	38,800,000

	1983 Actual	1984 Actual	1985 Actual	1986 Appropration	1986 After Seqestering	1986 Revised Estimate.	1987 Estimate
National Institute of Neurological and Communicative Disorders & Stroke...	17,326,000	20,094,000	27,797,000	30,410,000	29,090,000	28,430,000	28,130,000
National Institute of Allergy & Infectious Diseases..................	35,162,000	36,099,000	46,940,000	47,994,000	45,897,000	45,715,000	43,983,000
National Eye Institute.....	28,946,000	33,957,000	41,472,000	45,300,000	43,350,000	42,000,000	41,750,000
National Institute of Environmental Health Sciences..................	12,478,000	14,475,000	16,948,000	17,643,000	16,536,000	16,536,000	16,357,000
Division of Research Resource..................	18,899,000	21,809,000	21,223,000	21,499,000	20,575,000	20,575,000	18,627,000
Total, NIH..................	365,426,000	409,616,000	506,224,000	534,458,000	509,395,000	504,903,000	497,250,000
Alcohol, Drug Abuse and Mental Health Administration:							
Child and Adolescent Mental Health.............	18,210,000	24,474,000	30,231,000	33,269,000	32,345,000	24,943,000	24,592,000
TOTAL, PHS...........	433,068,000	485,893,425	599,578,440	935,751,194	607,373,705	588,767,864	578,865,000

HEALTH RESOURCES AND SERVICES ADMINISTRATION
Bureau of Health Care Delivery and Assistance

MATERNAL AND CHILD HEALTH

The Maternal and Child Health (MCH) Services Block Grant program was initiated in Fiscal Year (FY) 1982. The program combined the following former categorical grant programs: MCH Grants to States; MCH Research and Training; SSI Disabled Children's program; Genetic Diseases; Hemophilia; Sudden Infant Death Syndrome; Lead-based Paint; and Adolescent Health.

The Block Grant program provides block allocations to the States to allow the States to provide a broad range of health care services, including preventive, primary care, and rehabilitative services, to mothers and children. In FY 1984 and FY 1985, 85 percent of total funds available were allocated to research and training, genetic diseases projects, hemophilia treatment, and special projects of regional or national significance. In 1985, 420 such grants were supported.

In FY 1986, 85 percent of total funds will be allocated on a block basis and 15 percent will be available for special projects grants of regional and national significance. All 57 States and Territories will receive and administer the MCH Block Grants. In addition, 384 projects will be supported with 15% funds.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Bureau of Health Professions

MATERNAL AND CHILD HEALTH

Under the nursing programs, registered nurses are prepared as nurse midwives, obstetrical/gyncological nurse practitioners and pediatric or school nurse clinicians and practitioners. Nurse midwives provide primary health care services for women from menarche to menopause including care of childbearing families and healthy newborns. The obstetrical/gynecological nurse clinicians and practitioners are prepared to manage antepartum and postpartum care as well as common gynecological conditions and family planning. The pediatric and school nurse practitioners focus their attention on the primary health care of children from infants through adolescence. Regardless of the nurse practitioner's or nurse midwife's areas of specialization in maternal and child health, the basic tenets of their health oriented services are health promotion and maintenance through teaching, guidance, counseling and health screening activities. The Nurse Practitioner program spent $4,664,880 in maternal and child health in FY 1985.

Nursing Research Grants awarded $910,792 in FY 1985 to support projects studying a variety of aspects of maternal and child health care. Several ways of enhancing prenatal care (better education of the mother about her pregnancy and her baby and improved preparation for labor) are being evaluated in terms or delivery and newborn outcomes. Early infancy is the focus of studies looking at breast/feeding and at mother-infant interaction with normal infants as well as with infants having development handicaps or congenital heart disease. Improved parenting is an intended result of three new interventions designed to educate first-time parents; to train parents of children with anti-social behavior; and to achieve realistic parental expectations based on normal child development thereby preventing child abuse. Delivery of service is being examined in terms of stresses in the Neonatal Intensive Care Unit and use of Well Baby Clinics.

Activities in Advanced Nurse Training in FY 1985 included support for educational programs to prepare clinical nurse specialists to care for women in the child bearing years, infants at high risk and children through adolescence. Approximately $2,137,694 was spent in this area.

Public health funds have been used to support traineeships to improve administration and competency of personnel in maternal and child health programs. In FY 1985 approximately $170,977 was awarded for traineeship support in maternal and child health.

In FY 1985 two physician assistant programs received specific funds for their maternal and child health activities. St. Louis University received $8,194 and University of Colorado Health Sciences Center received $5,000 for their individual efforts. An additional seven program indicated efforts in this area.

Five Area Health Education Center programs indicated activities targeted toward the training of maternal and child health, with an estimated impact on 130,000 individuals in FY 1985. A total of $26,000 was funded to three programs (University of Arizona, Michigan State University and Oklahoma Community AHEC). The largest award being $20,000 to the University of Arizona.

Centers for Disease Control
Immunization
Maternal and Child Health

The Centers for Disease Control has provided project grant and technical assistance to State and local health agencies in support of their childhood immunization programs snce 1963. Initially, support was funded for immunization programs against poliomyelitis, diphtheria, pertussis, and tetanus. Later, as new vaccines became available, support was focused on the control of measles, and then rubella. As backlogs of unprotected children were reduced for these diseases, support for more comprehensive immunization programs was provided. By calendar year 1974, reported cases of measles, rubella, and poliomyelitis had reached what was then all time lows. As a result, concern for immunization programs began to relax and support declined, and by 1977 immunization levels against the childhood vaccine-preventable diseases ranged from 45-75 percent (for children under age 15 years).

As a result of this decline in immunization levels, a National Immunization Initiative was launched. Federal level grant support has enabled projects to carry out effective immunization programs. Their intensive efforts have had a profound impact on the health of the Nation's children. Reported measles cases declined from 385,156 in 1963 (the year measles vaccine was licensed) to a record low 1,436 in 1983 A total of 2,704* cases were reported in 1985.

Reported rubella cases declined from 57,686 in 1969 (the highest number of rubella cases since the disease became reportable) to a record low of 604* cases reported in 1985. A total of 752 cases was reported in 1984.

Mumps became a nationally reportable disease in 1968 and 152,209 cases were reported. A record low of 2,886* cases was reported in 1985.

In 1963, a total of 17,135 cases of pertussis was reported. An all-time low occurred in 1976 when 1,010 cases were reported. During 1985, a total of 3,275* cases has been reported, compared to 2,276 cases in 1984.

Diphtheria, tetanus, and paralytic polio had very low numbers of cases in 1963 when compared to measles. Respectively, there were 314, 325, and 396 cases reported. During 1985, totals of 2*, 71*, and 5* cases of diphtheria, tetanus and paralytic polio have been reported, respectively. During 1985, there were only two cases of tetanus in children under 15 years of age and no cases of diphtheria in children under 15 years of age.

In 50 States, the District of Columbia and New York City, immunization records of approximately 4.5 million school enterers were reviewed for the 1984/85 school year. The immunization levels determined by this assessment were 98 percent for measles, polio, mumps, and rubella, and 97 percent for DTP/Td.

*Provisional data

Appropriate administration of safe and effective vaccines remains the most cost-effective method of preventing human suffering and reducing economic costs resulting from vaccine-preventable diseases. Since 1963, the Centers for Disease Control has provided project grant support to assist State and local health agencies in planning, developing, and conducting childhood immunization programs. The funding for FY 1985 was 42.4 million.

Benefit-cost analysis of immunizations demonstrates high rates of return and indicates that immunization programs make an important contribution to health sector cost containment efforts as well as to the quality of life of the communities served. For example, it is estimated that measles immunization currently saves approximately $500 million per year, and that polio immunization saves about $1 billion per year. Over 59 million cases of measles and 19,500 cases of mental retardation have been averted, and 5,900 children's lives have been saved because of measles immunization.

State and local immunization programs, supported by these funds and other Federal resources, have raised immunization levels higher than ever before, and reduced the reported occurrance of most vaccine-preventable diseases to the lowest levels ever, or to near record lows. The following data describe the latest immunization levels and reported disease incidence:

	Immunization Levels (National Weighted Results)		Reported Cases	
Disease	1983-84 School Year	1984-85 School Year	1984	1985*
Measles	98%	98%	2,587**	2,704
Rubella	98%	98%	752**	604**
Polio	97%	98%	8	5**
Diphtheria	97%	97%	1	2**
Tetanus	97%	97%	74	71**
Pertussis	97%	97%	2,276	3,275
Mumps	97%	98%	3,021**	2,886**

*Provisional Data
**Record low

With the attainment of these immunization levels, major epidemics of these diseases have been eliminated and the backlog of underimmunized school-age children has been virtually eliminated. In addition, grant resources support local disease surveillance and outbreak control activities, local assessment of immunization levels and coverage, local public awareness activities, and local laboratory services.

These State and local activities are complemented by activities performed at CDC which can either be accomplished better at the national level or which are more cost effective to perform centrally rather than being duplicated in each State and Territory. These activities include providing technical assistance and consultation in management practices and program operation methods; developing national goals for the prevention and control of childhood vaccine-preventable diseases and the strategies for achieving these goals: reviewing and evaluating State and local immunization programs; maintaining a stockpile of vaccine and jet injector equipment for use to control epidemics or in the event of disruption in vaccine supply; maintaining a mechanism for the saving of millions of dollars annually in the consolidated purchase of vaccines: providing national surveillance of vaccine-preventable diseases and prompt epidemic assistance in the investigation and control of disease outbreaks: providing laboratory reference services; rapidly identifying of problems of national significance (e.g., the identification of a "hot lot" of vaccine): developing recommendations for the appropriate use of vaccines; assessing national immunization levels: laboratory proficiency testing and quality control: and conducting studies and investigations to determine the safety, efficacy, and appropriate use of new and current vaccines.

The following 1985 accomplishments reflect the continuing progress being made as a result of multifaceted immunization programs involving a coordinated approach whereby Federal, State, and local governments have worked together toward a common goal:

a. Indigenous measles has been all but eliminated from the United States.

b. Only two case of diphtheria and five cases of polio were reported (provisional data).

c. Only two cases of tetanus and no case of diphtheria were reported in children under age 15 (provisional data).

d. Over twenty-two million doses of childhood vaccine were administered in the public sector.

e. Approximately 16.1 million doses of vaccine were purchased through CDC vaccine contracts for use in State and local immunization programs.

f. All 50 States and the District of Columbia have immunization laws requiring immunization prior to the first entry into school. Forty-six of these areas now have Kindergarten through Grade 12 immunization requirements.

g. Forty-six reporting areas have implemented hospital-based maternal immunization education programs which reach 90 percent of targeted hospitals.

h. Standard immunization record cards have been adopted in all 50 States and the District of Columbia.

The long-range goal of the immunization program is, through immunization, to eliminate indigenous measles, rubella, and congenital rubella syndrome from the U.S. entirely, and to reduce poliomyelitis (polio), mumps, diphtheria, pertussis and tetanus to levels so as not to be significant public health problems in the United States. The objectives of the program are to assist in achieving:

- By 1990, reductions in the reported incidence rate of:
  - Measles to fewer than 500 cases per year, all import-associated.
  - Mumps, rubella, and pertussis to fewer than 1,000 cases per year.
  - Diphtheria and tetanus to fewer than 50 cases per year.
  - Polio cases to fewer than 10 cases per year.
- By 1990, increases in the number of children immunized so that:
  - Ninety percent of children will be immunized against measles, mumps, rubella, diphtheria, pertussis, and tetanus by the end of their second year of life.
  - Ninety-five percent of children attending licensed day-care centers and kindergarten-grade 12 should be fully immunized.
- By 1990, refined and improved surveillance and evaluation systems so that:
  - At least 95 percent of all children through age 18 have up-to-date official immunization records in a uniform format using common guidelines for completion of immunizations.
  - At least 90 percent of those hospitalized and 50 percent of those not hospitalized with vaccine-preventable diseases are reported.

CENTERS FOR DISEASE CONTROL
CHILDHOOD LEAD POISONING PREVENTION
MATERNAL AND CHILD HEALTH

Lead is ubiquitous in the environment, and adults and children are exposed to it from many sources--air, water, food, dust, soil, and paint. Young children, especially those 1-5 years of age, are much more susceptible to available lead than are adults because children absorb a higher proportion of the lead they ingest, and their developing brain is more vulnerable to damage from lead.

Childhood lead toxicity is prevalent in many communities, large and small, located in all sections of the country. For example, the "Second National Health and Nutrition Examination Survey, 1976-1980", conducted by the National Center for Health Statistics to measure blood lead levels in the general United States population, found that 4 percent of all children ages 6 months-5 years had elevated blood lead levels. Positivity rates ranged from 2.1 percent in rural areas to 11.6 percent in inner cities. Lead toxicity produces serious adverse health effects in children, including severe mental retardation, seizure disorders, subtle psychologic deficits, behavioral disorders, and learning disabilities. These latter three consequences are noteworthy because they result from levels of lead exposure previously considered safe and occur in children who are asymptomatic. Because of this and the high prevalence of the disease, the Centers for Disease Control (CDC) recommends that all children ages 1-5 be screened for lead toxicity. An expert committee recommended rewriting the CDC lead statement with emphasis on lowering the threshold level of concern for both blood lead and erythrocyte protoporphyrin. The new document, Preventing Lead Poisoning in Young Children, was distributed in 1985.

From 1972 through 1981, CDC administered a Childhood Lead Poisoning Prevention Project Grant Program. During this period, categorical grant funds totaling approximately $90 million were provided to more than 100 communities in 35 States. These programs have reported the screening of 4,252,000 children with 245,000 (6.0%) identified with lead toxicity.

Effective October 1, 1981, the Childhood Lead Poisoning Prevention Grant Program, administered by CDC, was consolidated into the Maternal and Child Health Block Grant, administered by the Health Resources and Services Administration (HRSA). Under this block grant, States are responsible for providing guidance to local operating programs on the medical, environmental, and management aspects of childhood lead poisoning prevention. CDC will continue to provide technical assistance.

In the past, CDC has provided technical assistance to HRSA on incorporating routine screening for lead toxicity in HRSA--affiliated programs. During fiscal year 1986, CDC will make available to HRSA, States, and communities technical assistance focusing on outreach, resource development, environmental epidemiology, lead hazard reduction, and laboratory services. In cooperation with HRSA, CDC continued operating the Blood Lead and Erythrocyte Protoporphyrin Proficiency Testing Programs - with over 200 laboratories participating from all parts of the country.

NATIONAL INSTITUTES OF HEALTH

National Institute of Child Health and Human Development

MATERNAL AND CHILD HEALTH

Since 1962 the National Institute of Child Health and Human Development (NICHD) has dedicated itself to studying the health of mothers and children. It supports and conducts research directed toward ensuring the optimal outcome of the six million pregnancies that occur in the United States each year, and toward maximizing the health potential for the 3.7 million infants born annually.

Special foci of study are pregnancy and fetal development, high risk pregnancy, low birth weight and premature birth, childhood growth and development, diseases and disorders of infancy and childhood, nutrition, obesity, sudden infant death syndrome, and psychological factors affecting maternal and child health.

LOW BIRTH WEIGHT

The preeminent infant health problem in the United States today is low birth weight--that is 2,500 grams (5 1/2 pounds) or less. It is associated with two-thirds of all deaths during the first year of life and three-quarters of all deaths of newborns. Babies of very low birth weight--1,500 grams (3 1/2 pounds) or less--are particularly susceptible to death or disability. Although the proportion of low-birth-weight babies has been slightly reduced during the past decade, there has been no reduction in the proportion of babies of very low birth weight.

The United States' poor international ranking in infant mortality is not in keeping with its status as a wealthy nation committed to health. The high mortality is attributable almost entirely to the problem of low birth weight. In 1984, NICHD launched a research initiative focused on low birth weight and its causes--premature labor (preterm birth), intrauterine growth retardation, or a combination of these two.

NICHD sponsors several projects aimed at exploring racial and socioeconomic differences in low-birth-weight deliveries. The Better Babies Project in Washington, D.C., not only studies low birth weight but also attempts to prevent it through intervention during pregnancy. All pregnant women in a target area will be identified early in pregnancy, linked with medical and social services, and trained to recognize signs of premature labor early when premature delivery can still be stopped. Smokers, drinkers, and underweight women will be offered special help. The effect of such intervention will be assessed by comparing the rate of low-birth-weight deliveries in the target area with those in comparable areas.

Low birth weight is twice as common among black as among white babies, even when controlling for risk factors. The differences are under investigation. In a study of low birth weight, grantee Richard Ward and colleagues at the University of British Columbia in Vancouver, Canada, found that ethnic groups other than blacks differed from whites in fetal growth. The growth curve for East Indians, Japanese, and Chinese was lower than that for whites and Native Americans except during the last 8 to 10 weeks of gestation when the curves are identical. It appears that birth-weight differences are established early in gestation; interventions late in pregnancy are unlikely to make much difference.

Much of the improvement in the survival rates for low-birth-weight babies is attributable to sophisticated treatment in intensive care nurseries. However, a team of investigators from a drug surveillance program headed by grantee Dr. Allen A. Mitchell of Children's Hospital in Boston, Massachusetts, has documented some potentially dangerous changes in drug use over the past few years. Heparin, a drug used to thin blood to prevent clotting, is associated with a fourfold increase in the risk of intraventricular (brain) hemorrhage, a major cause of death and disabililty in newborns. Yet it is routinely used to help in catheterization. Morphine use has also increased. Preliminary data from the study show that exposure of sick infants to some drug additives may occasionally cause serious and even fatal reactions.

Preterm births

Respiratory distress syndrome afflicts a large proportion of premature babies despite significant advances in understanding, preventing, and treating the disorder. Biochemical techniques to predict lung maturation *in utero* are not always useful. Therefore, grantee Dr. Paul L. Carson, at the University of Michigan in Ann Arbor, is assessing the effectiveness of ultrasound for predicting respiratory distress syndrome after delivery. He has shown in lambs that lung reflectivity is an index of maturity, and certain patterns correlate with immature lung status. If ultrasound can predict when the human lung will mature or respond to stimulants to maturation, its use will significantly improve the health prospects of premature infants.

To design strategies for preventing premature labor, investigators are studying events that accompany the onset of labor. In one NICHD-supported project, grantee Dr. Paul C. MacDonald and colleagues at the University of Texas Health Science Center in Dallas are studying a substance called platelet-activating factor (PAF), which is detectable in amniotic fluid only after labor begins. He has found that PAF synthesis is stimulated by calcium--further support for assertions that ionized calcium plays a central role in the biochemistry of labor.

Grantee Dr. Peter W. Nathanielsz and colleagues at Cornell University in Ithaca, New York, are investigating nonlabor uterine contractions. Studies of pregnant sheep and rhesus monkeys have enabled them to describe precisely the transition from nonlabor contractions to labor and birth. The uterine muscle is not completely quiescent during pregnancy. In the transition to labor, electric bursts become first shorter and then more frequent. Finally, the electric bursts increase intrauterine pressure. This normal transition pattern can now be studied experimentally to determine controlling factors.

Tocolytic drugs, which can sometimes suppress premature labor, have recently become available to physicians. Concern has arisen over the cardiovascular effects these agents may have on both mother and fetus. Grantee Dr. Rufus H. Holbrook, at the University of California at San Francisco, is exploring the distribution of blood flow in the fetuses of pregnant sheep treated with a tocolytic drug that increases blood flow to the fetus's vital organs. Such redistribution may result from fetal hypoxia (lack of oxygen) secondary to reduced uterine blood flow in mothers receiving the drug.

Intrauterine growth retardation

Intrauterine growth retardation, which results in babies small for their gestational age, is associated with increased rates of sickness and death just before, during, or soon after birth. A team of investigators headed by Dr. Robert Goldenberg at the University of Alabama in Birmingham is working under an NICHD contract to identify risk factors for intrauterine growth retardation. Their aim is to distinguish mothers who repeatedly bear low-birth-weight babies from those who bear single, unexpected ones. Women will be recruited for the study early in pregnancy and assessed by ultrasound. Babies who are small for gestational age will be examined at birth and throughout the first year to determine catchup growth and attainment of developmental milestones.

PREGNANCY AND FETAL DEVELOPMENT

Nausea and vomiting are common during pregnancy. Dr. Mark A. Klebanoff, an NICHD intramural scientist, has shown that, if not excessive, nausea during pregnancy actually is associated with a slightly more favorable pregnancy outcome. Women who did not vomit were at greater risk for losing their fetuses than those who did vomit. The scientists are analyzing these results in the context of the hormones thought to be responsible for vomiting during pregnancy.

ENVIRONMENTAL HAZARDS

Many environmental hazards can cause abnormal development *in utero*. Among them are drugs, radiation, environmental chemicals, maternal infections and metabolic disturbances, and immunologic reactions.

A controversy has recently erupted over the use of vitamin A and its structural analogs (retinoids) for the treatment of skin conditions and precancerous disease among pregnant women. Retinoid treatment of pregnant women during the first trimester has been linked with spontaneous abortions and birth defects.

Grantee Dr. Susan Donoghue and her colleagues at the University of Pennsylvania in Philadelphia have found that the systems for transporting, storing, and using vitamin A are all highly dependent on proteins. Therefore, study of metabolism of this vitamin in pregnant women and fetuses should include examination of the effects of protein intake. The researchers found that transport of vitamin A across the placenta is suppressed when the mother's stores of vitamin A are high and mobilized when stores are low. The decrease in transport with excessive maternal intake of vitamin A affords the fetus some, but not total, protection.

In an NICHD analysis of smoking during pregnancy, a strong association was found between tobacco use and spontaneous abortion of genetically abnormal fetuses, especially among older women. Laboratory and animal studies on alcohol, tobacco, caffeine, and marijuana use continue. It is hoped that the effects of individual or combined substance use during pregnancy can be determined.

Earlier studies have shown that infants of mothers who smoke during pregnancy may weigh 150 to 250 grams less at birth than babies of nonsmoking mothers. We now know that maternal smoking may cause premature birth as well as intrauterine growth retardation. Dr. Patricia H. Shiono and her intramural colleagues at NICHD studied pregnancy outcomes of 34,000 women and found that the likelihood of delivery before 33 weeks' gestation (38-40 weeks of gestation is normal) was increased about 60 percent in women smoking one or more packs per day.

Under the direction of Dr. Daniel Nebert, intramural researchers are studying the genes that encode drug-metabolizing enzymes, most of which are called P-450 proteins. They have mapped the human P_1-450 gene and are using recombinant DNA technology to assess genetic types so that they can identify persons at high risk for environment-caused birth defects, cancers, and toxicity.

NUTRITION

NICHD's nutrition research program focuses on human development from conception through adolescence, with emphasis on the prevention of nutrition-related diseases.

Data from the National Health and Nutrition Examination Survey, conducted by the National Center for Health Statistics, are being examined by NICHD scientists led by Dr. Barry Graubard. In this survey, participants were asked about their food intake and also underwent a medical examination for signs of nutrient deficiency or other ill health. Some of the NICHD analyses concern childhood obesity, the relationship between dietary adequacy and food supplement use, and an assessment of the diets of pregnant women, whose increased nutrient needs put them at increased risk of malnutrition.

Research priorities in infant nutrition include the needs of normal, premature, and growth-retarded infants, with emphasis on the different needs of normal infants and low-birth-weight ones.

In 1979, thousands of infants were fed Neo-Mull-Soy, a formula deficient in chloride. NICHD's Epidemiology and Biometry Research Program under Dr. Heinz W. Berendes took the lead ina Congressionally-mandated study to determine whether these children suffered long-term effects such as delayed mental development or decreased school performance. An earlier evaluation suggested that the duration of exclusive feeding of Neo-Mull-Soy was related to early motor development problems or decreased school performance. Efforts to generate an unbiased sample of children fed Neo-Mull-Soy and examine them for possible long-term effects are still under way.

Recent findings on particular nutrients are summarized below.

Iron--Iron deficiency is the most common nutritional problem in the world. Infants, especially those of low birth weight, women in their childbearing years, and the disadvantaged are at the greatest risk of iron deficiency, which leads to greater susceptibility to infections. Grantee Dr. Bruce Mackler at the University of Washington in Seattle is studying the role of iron, an integral part of many enzymes, in the immune system. Working with rats, they are determining whether iron deficiency problems in the immune system are permanent or can be reversed by administering iron.

Zinc--Zinc deficiency is associated with impaired immunity. Prenatal or post-partum zinc deficiency slows or stops development of the immune system. Laboratory studies by grantee Dr. Eric M. Gershwin and his colleagues at the University of California at Davis show decreased antibody responses in zinc-deficient animals. Zinc administration quickly corrects some deficiency abnormalities but has a major side effect, increase in the size of the thymus gland.

Manganese--Grantee Dr. Lucille S. Hurley and her colleagues at the University of California at Davis have recently established that manganese deficiency can result in fetal malformation and death in mammals. She found that the harmful effect of low dietary manganese is not due to secondary zinc deficiency, as had formerly been theorized.

OBESITY

Obesity is a major public health problem in the United States. Being overweight is linked with diabetes mellitus, cardiovascular disease, hypertension, and some kinds of cancer.

Grantee Dr. Alexander F. Roche and colleagues at Wright State University in Dayton, Ohio, are examining the antecedents of obesity from infancy through adulthood in thousands of people. They have found that infant obesity was not a predictor of adult obesity. However, obesity from age 4 on does predict adult obesity with an accuracy that increases with the age at which obesity begins. This means that intervention would be more effective during preschool years than during infancy.

Studies of obesity in animals include investigations of metabolic factors important in the development of obesity. In experiments on rats, grantee Dr. Mary R. Greenwood at Vassar College, Poughkeepsie, New York, found that the activity of enzymes for metabolizing fats was much higher in obese than in lean rats. Exercise and food restriction had some effect on obese rats but did not change this enzymatic activity or reduce the size of adipose cells to normal. Grantee Dr. Roy J. Martin and colleagues at the University of Georgia in Athens, in experiments on the genetically obese pig, have shown that the adipose cell is central to the development of obesity. In prenatal development, many factors act in concert to regulate adipose cell development. The roles of the hypothalamus and pituitary are being studied as a suspected cause of adipose cell abnormalities.

INFECTIONS

Neonatal infections

Many newborns develop infections but the death rate from them has dropped from 85 percent in the 1940's to 20 to 40 percent today. Neonatal supportive care and antimicrobial therapy are responsible for most of this advance. Unfortunately, many researchers consider a further decline in the death rate unlikely because of inherent defects in the newborn's immune system.

Though that system is usually intact, it is immature and may not function at the highest possible level. A varying quality and quantity of the mother's immunoglobulin crosses the placenta during pregnancy and conveys some immunity. That immunologic protection ends at birth, although the mother can continue to transfer some degree of immunity through breastfeeding.

NICHD's current studies focus on the inadequate infection-fighting capacity of newborns. Studies are also being conducted on the immune responses of sick and malnourished infants and low-birth-weight babies.

Bacterial diseases

NICHD intramural researchers Drs. John Robbins and Rachel Schneerson continue their work on the processes of invasive bacterial diseases of infants and children and methods of preventing these diseases. Their studies focus on pneumococci and on Haemophilus influenzae type b. These two bacteria remain a serious cause of sickness and death in infants and young children despite the availability of effective antibiotics and supportive therapy.

Pneumococcus is a major cause of otitis media, a common, often chronic, infection which is a major cause of hearing loss. This organism also causes meningitis and pneumonia. The current pneumococcal vaccine does not satisfactorily prevent otitis media in infants and children, the age group with the highest attack rate, because its protection is age related and it does not induce a booster response in those vaccinated. Therefore, Dr. Robbins and his team are working toward developing a more effective vaccine. They have synthesized a variant of the present vaccine and are analyzing its immune effects and other properties.

H. influenzae type b is the leading cause of bacterial meningitis in infants and children, as well as a major cause of septicemia and pneumonia. An H. influenzae type b vaccine, initially developed in NICHD laboratories in the early 1970's, was recently licensed. The American Academy of Pediatrics and U.S. Public Health Service recommend that it be used for children over 2 years of age, as well as those 18 months old if they are in day care centers. The National Institute of Allergy and Infectious Diseases (NIAID) sponsored extensive trials of this vaccine in Finland, and established that the vaccine is safe and effective, though it does not offer sufficient protection for the age group most often struck by Hib infections--children under 18 months of age.

In response to this problem, NICHD conducted and NIAID supported research that resulted in the development of ways to bind the vaccine to other proteins, producing a "conjugate" vaccine. The type b conjugate vaccine was synthesized by NICHD intramural scientists. Extensive testing in laboratory rodents and in juvenile and infant primates established that it is indeed an improved vaccine that worked in infancy. It has increased immune properties and confers booster effects.

Another Hib polysaccharide-protein conjugate vaccine, which is more readily recognized by an infant's immature immune system, has been developed through NIAID support. This vaccine has been given to several hundred infants at 2, 4, and 6 months of age. In preliminary trials, the vaccine was shown to be safe, and capable of inducing an immune response at a protective level following the third injection. Dr. Joel Ward, an NIAID contractor at Harbor-UCLA Medical Center, Torrance, California, is currently performing a large-scale trial of a Hib conjugate vaccine in Alaskan Native infants.

Pertussis, or whooping cough, had virtually been eliminated in the United States through mass immunization. However, adverse reactions to the vaccine have led to a reluctance to accept it, and whooping cough cases have now increased. A number of new and potentially safer vaccines are in various stages of development and testing.

Recently pertussis toxin (PT) was identified as a major stimulant of pertussis immunity. NICHD intramural researcher Dr. Ronald Sekura and colleagues have devised a novel method for neutralizing PT's toxic action while retaining its ability to stimulate immunity. They have developed a method for producing the experimental vaccines in sufficient quantities for clinical trials. The detoxified PT shows only minimal levels of toxic activity and protects immunized animals against the lethal effects of PT. This new detoxified PT will be evaluated in adults, then infants and children. Initially, the detoxified pertussis vaccine will be tested along with the conjugate vaccine to H. influenzae type b in a double-blind trial in Sweden, where there is a high incidence of whooping cough.

Another pertussis vaccine, consisting principally of two major pertussis proteins, has been compared to conventional whole cell vaccine in American children. The new vaccine was originally manufactured in Japan and has been used widely there since 1981. Following favorable results in 4 to 6 year olds, as well as 18-month and 6-month-old children, the acellular vaccine is being tested in infants 2, 4, and 6 months of age. Dr. Peter Wright at Vanderbilt University in Nashville, Tennessee, and Dr. Robert Belshe at Marshall University in Huntington, West Virginia, have conducted these trials in NIAID's contract-supported vaccine evaluation units.

The same investigators will be testing a new, highly purified acellular pertussis vaccine developed by the Michigan Department of Public Health under a NIAID contract. Children aged 4 to 6 years and 18 months will receive the vaccine at Vanderbilt University. Because this is a new vaccine, investigators will know which children are receiving the vaccine and will be particularly alert to any problems that might be attributed to vaccine side effects. Subsequently, a double-blind study of this vaccine will be conducted at Marshall University in infants 2, 4, and 6 months of age.

NIAID is also collaborating with the Swedish National Bacteriological Laboratory (SBL), Stockholm, in efficacy trials using two different Japanese-manufactured acellular pertussis vaccines in infants 6 to 10 months old. The Swedish trials should answer the critical question of whether these vaccines will provoke an antibody response that correlates with sufficient protection against infection. If so, they would serve as prototypes for other acellular pertussis vaccines.

Typhoid fever, another bacterial disease, is a serious cause of sickness and death in underdeveloped countries. Dr. John Robbins and his group in the NICHD Intramural Research Program have produced a new vaccine for typhoid fever. Clinical trials of this vaccine will begin soon in Nepal and India. Tests on volunteers have led to much better methods of identifying carriers of typhoid fever who do not exhibit symptoms. This constitutes a step toward effective control of typhoid.

DISEASES OF CHILDHOOD AND INFANCY

NICHD research shows that treatment with cysteamine slows the presently irreversible progress of nephropathic cystinosis, a metabolic disease that usually leads to kidney failure before the age of 10. In a 7-year clinical trial, intramural researcher Dr. William Gahl has shown that cysteamine therapy begun before age 3 leads to improved growth and slows kidney deterioration. It is not yet known whether such therapy begun very early in life can fully protect against kidney failure.

Patients with disorders of glycogen (animal starch) storage have previously been treated by complex procedures to prevent fatal hypoglycemia (low blood sugar). Dr. James B. Sidbury, NICHD intramural scientist, has shown that these children can be effectively treated by oral administration of cornstarch, a simple and inexpensive therapy.

CHILDHOOD GROWTH AND MATURATION

Intramural researcher Dr. Fernando Cassorla and his team compared the levels of the growth regulatory hormone somatomedin C (SmC) in children with precocious puberty, age-matched controls, and those who reached puberty normally. SmC levels correlated with sexual maturation. Treatment of children with precocious puberty resulted in much greater decreases in growth rate than in SmC level. It appears that SmC affects pubertal growth but is not its principal modulator.

Turner's syndrome is a group of deformities in which an ovarian deficiency interferes with growth. NICHD intramural researchers led by Dr. Gordon B. Cutler, Jr. used low doses of estrogen to treat girls with Turner's syndrome. The scientists found that such doses sustained growth without undue bone advancement. In contrast, the popular therapy of almost 10 times the dose used in this study may reduce patients' ultimate height and actually be harmful. Low-dose estrogen therapy is an important advance in the treatment of this disease.

In the past year it was found that human growth hormone may be contaminated with the infectious agent for Creutzfeldt-Jakob disease, so it is no longer available for clinical use. Studies to identify treatment alternatives for children with short stature have therefore become more important. NICHD intramural scientist Dr. George R. Merriam has been studying the use of growth hormone-releasing hormone (GHRH)--produced by recombinant DNA technology--on these children. Repeated doses of GHRH stimulated growth in half of the children tested, more so than standard doses of human growth hormone. GHRH may be an effective alternative to growth hormone in selected patients with growth hormone deficiency.

PSYCHOLOGICAL FACTORS

NICHD investigators under the direction of Dr. Frank Pederson are examining mother-infant separations, an increasing occurrence today. Separations because of the mothers' employment occurred more frequently and for longer duration than other types of separations, and began earlier in infants' lives. They usually went to other homes where children were present. Separations for other reasons--such as classes, sports, or volunteer work--were less patterned or predictable.

Infants whose substitute care arrangements involved experience with other children were more likely than others to have secure relationships with their mothers at 1 year of age, regardless of the mother's employment status. This finding is noteworthy in light of earlier evidence linking early childhood peer experience with greater autonomy and more advanced levels of play. Data on nonhuman primates also indicate that early peer experience can partly compensate for maternal absence.

National Cancer Institute

Cancer is second only to accidents as the leading cause of death among children. It is estimated that by the end of 1985, more than 1,600 children will die of cancer, about half of them from leukemia. (Leukemia is a cancer of the blood that develops in the bone marrow, the body tissue that produces blood cells.) More than 40 percent of childhood cancers occur in the very young--age 4 and under. Yet, because of new advances in cancer research and treatment, mortality among children with cancer has declined markedly.

Dr. David G. Poplack, NCI intramural scientist, has been evaluating the use of high-dose methotrexate to prevent leukemia from invading the central nervous system (CNS).

In a study of 176 children with acute lymphocytic leukemia (ALL), Dr. Poplack and his colleagues have compared high-dose methotrexate as central nervous system preventative therapy to the normal regimen of cranial radiation and methotrexate injected into the spinal canal. The hypothesis was that high-dose methotrexate infusions alone would be equally effective and less toxic than therapy that included cranial radiation.

Preliminary results demonstrated that 82 percent of the 131 "standard risk patients" were alive and disease-free at 2 years, while 60 percent of the remaining 45 patients at high risk when therapy began were in remission at two years. The overall remission for the entire group was 76 percent. Thus, Dr. Poplack and associates have demonstrated that excellent results may be obtained in children with ALL without treatment with cranial radiation. Long term evaluation of toxic effects on the CNS are now under way.

Soft-tissue sarcomas are cancers originating in bone, cartilage, muscle, fibrous connective tissue, or fatty tissue. Under the direction of Dr. James Miser, the NCI is studying a combination of chemotherapy drugs plus autologous bone marrow rescue (bone marrow from the patient is frozen and then infused at a later date back into patient) in the treatment of soft-tissue sarcomas.

Fifty-one previously untreated high-risk patients with solid tumors were given intensive chemotherapy with vincristine, adriamycin and cyclophosphamide for five courses. This was followed by radiation therapy and autologous bone marrow transplantation. After 6 months, 88 percent of the patients had complete remission (40 percent by six weeks) of their tumor; three percent had partial responses. Dr Miser believes that this form of intensive therapy is successful in inducing complete remission in most patients.

Children's Hospital of Los Angeles (CHLA), a pediatric referral center for the Pacific coast, has one of the largest pediatric oncology services in the United States. Dr. Jorge Ortega and associates there are conducting clinical investigations with 540 patients to establish the best modes of chemotherapy.

They are testing and modifying dosage schedules of four experimental chemotherapeutic agents and a number of standard prescription anticancer drugs for safety and efficacy. They are also testing better antimicrobial dosage schedules for infections which often occur in young cancer patients.

Neuroblastoma, a cancer of the sympathetic nervous system, is a cancer composed of immature nerve cells. Most patients with neuroblastoma have widespread disease incurable by currently known methods. More than half of all cases appear before age two. By the end of this year, more than 250 children will die of neuroblastoma and another 525 cases will be newly diagnosed.

Dr. Garrett M. Brodeur and his staff at CHLA are studying the clinical implications of oncogene amplification (extra copies of the oncogene) in human neuroblastoma. An oncogene is a gene which may transform a normal host cell to a cancerous one. Dr. Brodeur believes that the number of copies of a particular oncogene known as N-myc plays an important role in the spread of certain neuroblastomas. Increasing numbers of the gene indicates a decreased probability of patient survival.

His study of 89 patients corroborates two previous NCI intramural studies on the N-myc gene. He is also working on ways to inhibit the transformation of a normal cell into a cancerous one.

National Heart, Lung, and Blood Institute

Severe infections in children and older patients with sickle cell disease and other related hemoglobin disorders are largely related to the loss of function of the spleen.

The primary technique for assessing that function in these patients has been serial spleen scans involving the injection of a radioactive substance. While this method has been considered the best, the procedure is expensive and involves exposing the patient to radiation.

The NHLBI-funded Cooperative Study of Sickle Cell Diseases (CSSCD) which involves 22 institutions around the country has recently developed an economical, sensitive blood test to measure splenic dysfunction: counting the number of "pocked" or "pitted" red blood cells.

Spleen scans using the radioactive substance were carried out simultaneously to correlate the number of pocked red cells with the level of splenic function.

Results of this study, involving large numbers of children, showed that nearly all of them with normal spleen scan had less than 3.5 percent pocked red blood cells. Patients with detectable splenic dysfunction had more than that, the percentage of pocked red cells increasing with decreasing spleen function.

Although research is continuing, the clinicians involved in this study conclude that frequent blood tests to determine the percentage of pocked red cells may permit the physician to determine the onset of splenic dysfunction, and thus identify the point at which the child with sickle cell disease is at risk of developing severe bacterial infections.

NATIONAL INSTITUTE OF DENTAL RESEARCH

The National Institute of Dental Research (NIDR) conducts and supports research related to maternal and child health through its studies of dental caries, developmental biology, and cranio-facial malformations, and through behavioral research on children's responses to dental treatment and on adoption of methods to prevent tooth decay.

Finding ways to prevent and reverse of tooth decay is one of the important goals of the NIDR. An NIH consensus development panel has recommended the use of dental sealants in children, to increase protection against tooth decay. Children with newly erupted teeth can benefit most from sealants. Now, a research team supported by the NIDR has taken what may be a major step toward prevention of tooth decay in children by combining the inhibitive, restorative action of fluoride with the protection of sealants in a single, durable composition. The new sealants, developed by a team of NIDR grantees headed by Dr. H. Ralph Rawls of the Louisiana State University School of Dentistry, New Orleans, release fluoride by ion exchange. This process leaves the sealant structure intact while providing a long-term, steady release of fluoride. This research is part of a larger NIDR project examining the potential of fluoride ion-exchange resins for use in dental applications in which a long-term, low level of fluoride would be advantageous.

Other NIDR researchers have developed an experimental herpes vaccine that appears to offer protection against herpes simplex virus (HSV) types 1 and 2. Dr. Abner Notkins, director of the Intramural Research Program of the NIDR, and Dr. Bernard Moss, an intramual scientist with the National Institute of Allergy and Infectious Diseases (NIAID), found that the vaccine successfully prevented development of latent infection in mice by HSV type 1, the virus responsible for oral cold sores. The experimental vaccine was also found to protect against HSV type 2, or genital herpes. This vaccine is not a cure for persons already afflicted with herpes, but could protect persons who do not have herpes. The vaccine, therefore, would benefit young children and could become a standard part of pediatric care.

Using recombinant DNA technology and the developing tooth as a model, a team of dental scientists at the University of Southern California (USC) led by Dr. Harold Slavkin and researchers at the Baylor College of Medicine are studying how the layers of cells that form in the early stages of growth of the embryo send signals to each other to turn on or off the production of proteins required for each stage of tooth development. They have identified the gene responsible for the production of one of the major proteins required for formation of tooth enamel, and have determined the nuclectide (a building block of DNA) sequence for this gene. Now these scientists are trying to identify how the activating signal is transmitted from the adjacent tissue. An obvious goal is to be able eventually to correct anomalous growth and development.

Good nutrition is essential to maintain the health of the teeth and oral cavity. Researchers at the Eastman Dental Center in Rochester, New York recently have completed and NIDR-supported study of the cavity-causing potential of 22 common snack foods. Dr. John Featherstone and Sheila Mundorff found that the foods most likely to cause decay were raisins, bananas, cake, french fries, doughnuts, cupcakes, and confectioners sugar. Foods least likely to cause decay were peanuts, gelatin dessert, corn chips, yogart, and bologna. Foods in the moderate range were saltines, potato chips, corn starch, pretzels, graham crackers, chocolate, rye crackers, bread, and natural food snacks. In studying the chemical composition of each food, the investigators found that, in general, foods with a high fluoride, fat, or protein content cause the least tooth decay.

In another NIDR-supported project, Dr. Page Caufield and colleagues at the University of Alabama continue to study whether prevention in infants of infection by the bacterium *Streptococcus mutans* could reduce the development of cavities during early childhood. *S. mutans* is the chief bacterium that promotes tooth decay. The correlation between child's infection with *S. mutans* and the level of *S.mutans* in the mother's mouth is not known. These scientists have found that the use of simple antimicrobial agents such as fluoride and iodine lowers the level of *S. mutans* in mother's mouths. Now they are studying infants of these mothers to determine whether decreased transmission can give non-cavity causing microorganisms a chance to become well-established in the caries-prone sites of the infants' teeth and preempt colonization by *S. mutans*. It is hoped that this strategy can prevent caries development in the young child for long periods.

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) conducts and supports research in a variety of disease areas that relate to the health of mothers and children. These areas include juvenile arthritis, scoliosis, inherited connective tissue disorders, diabetes, endocrine disorders, and metabolic disorders such as cystic fibrosis. In addition, basic studies of metabolic processes though all developmental stages, including childhood, are reflected in many of the Institute's programs.

Intramural scientists Dr. David Pettitt and colleagues in Pheonix, Arizona, studied the offspring of Pima Indian women with diabetes during pregnancy to determine the risk of diabetes in their children. Such children were found to be at higher risk of developing diabetes than those whose mothers did not develop diabetes until later. These results suggest that the intrauterine environment plays a role in the development of diabetes later in the child's life.

In addition, these investigators have shown a correlation between the mother's glucose concentrations during pregnancy and the child's weight between the ages of 5 and 19 years. Obesity is known to be a risk factor in the development of noninsulin-dependent diabetes.

Dr. Ann Bennett, NIADDK grantee at the University of California, San Francisco, is using rats to study intrauterine growth in infants of diabetic mothers. Diabetic mothers often deliver "big babies" who are at risk for respiratory distress syndrome, hypoglycemia, and birth defects. Dr. Bennett is attempting to identify the mechanisms that cause excessive intrauterine growth and to identify early predictors of it so proper dietary or medical interventions may be utilized to reduce fetal and maternal complications.

Insulin is a hormone recognized for its role in maintaining normal glucose levels through its effects on fat, liver and muscle cells. However, investigators have identified a broader spectrum of insulin action including effects on fetal growth and cell differentiation.

NIADDK intramural scientists Drs. Flora de Pablo, Lluis Bassas, and Jesse Roth have examined the role of insulin in the early development of the chick embryo. Their research suggests that insulin in the chick embryo probably plays a developmentally significant role at early stages, perhaps regulating growth and differentiation. This information may provide a scientific basis for treatment of the pregnant diabetic and her developing baby.

The existence of a dietary requirement in humans for a specific type of fatty acid (omega-3) has remained an unsolved issue. Grantee Dr. William E. Connor, at the Oregon Health Sciences University, Portland, has developed a rhesus monkey model for a deficiency of alpha-linolenic acid (an omega-3 fatty acid) that is characterized at birth by visual defects and possible impairments in complex learning. These animals are being studied to determine if visual loss increases with increasing age, if juvenile animals show impairments in complex learning, and if remedying the deficiency corrects the biochemical and functional deficiencies. These studies should help to establish whether alpha-linolenic acid is an essential dietary element, and to elucidate the nutritional needs for this fatty acid through different stages of development.

Dr. Michael K. Hambidge, at the University of Colorado, Denver, is investigating zinc deficiency in pregnant and nursing women, in premature and full-term infants, and in the growing child. These studies of pregnant women have shown that iron supplementation may reduce maternal zinc levels. Other studies have shown a reduction in the zinc concentration in the milk of women who did not receive zinc supplements while breast feeding. This was especially so with prolonged lactation. These variations in maternal nutritional status during pregnancy and lactation may have potential significant effects on the fetus or infant.

Other NIADDK supported research of relevance to the health of mothers and children may be found in the separate reports on arthritis, rheumatic diseases, and related disorders; diabetes mellitus; and cystic fibrosis.

The National Institute of Neurological and Communicative Disorders and Stroke

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) conducts and supports research on maternal, infant, and child health problems that involve the brain and other portions of the nervous system.

At Children's Hospital in Pittsburgh, Pennsylvania, NINCDS grantee Dr. Charles D. Bluestone is testing therapies for the most common chronic childhood ear infection, otitis media with effusion. In this condition, fluid accumulates behind the eardrum, causing pressure that keeps the eardrum from reacting to sounds. One treatment suggested to correct this problem is myringotomy, a surgical procedure in which an incision is made in the eardrum to release the fluid. This year, Dr. Bluestone found evidence that children who have a drainage tube placed in the incision suffer less from otitis media than children who have the incision only. This finding indicates that myringotomy alone is not useful in treating otitis media patients.

In a study involving 222 infants and 540 older children with otitis media, Dr. Bluestone and his research team found hearing losses averaging 25 decibels. Such a loss could affect a child's ability to hear soft sounds like "f" and "s," and might result in later speech problems. The scientists also found that the pressure created by otitis media noticeably affected the childrens' sense of balance.

Data from the NINCDS Collaborative Perinatal Project, in which approximately 54,000 women and their babies were enrolled between 1959 and 1966, continue to yield information about how events or conditions around the time of birth affected the children born of these pregnancies.

Drs. Karin Nelson and Jonas Ellenberg, NINCDS scientisis, focused on data related to cerebral palsy. Analysis showed that maternal risk factors for cerebral palsy included mental retardation, seizure disorders, hyperthyroidism, or the taking of thyroid hormone or estrogen during pregnancy. Among the maternal factors that did not significantly affect the cerebral palsy rate were age, smoking history, diabetes, moderate hypertension, and induced labor. Labor duration was not found to be a risk factor for cerebral palsy.

The data also revealed risk factors predictive of very low birthweight (below 1500 grams or 3 1/3 pounds). These risk factors included maternal cigarette smoking, early vaginal bleeding, a malformed fetus, low birthweight of the previous child, and chorionitis. Chorionitis, an inflammation of the membrane that surrounds the fetus, was thought to be responsible for about 20 percent of the births under 1500 grams. Of the major low-birthweight predictors, only chorionitis, membrane rupture, and fetal malformation increased the risk of cerebral palsy.

Very low birthweight infants are at risk for brain hemorrhaging because their weak blood vessels may burst. This year, three NINCDS grantees--Dr. John M. Freeman at The Johns Hopkins University, Dr. Alan Leviton of Children's Hospital in Boston, and Dr. Nigel S. Paneth of New York's Research Foundation for Mental Hygiene--have begun to identify other factors that may increase this hemorrhage risk. The scientists will collect medical data on these infants for up to several years following birth, and will gather prospective information on maternal pregnancy and delivery. The additional risk factors they hope to define could help to separate infants at higher risk for hemorrhage from those children whose only risk factor is very low birthweight.

National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases places great emphasis on the conquering of infectious diseases that especially affect infants and children. Much recent research has been devoted to the development of new and improved vaccines against childhood diseases, and to the prevention of genital diseases transmissible from mother to newborn child.

A health problem of special concern to NIAID is the sharply rising incidence of genital herpes, particularly in women of childbearing age. Babies born to mothers with herpes infections risk death or severe damage to the central nervous system leading to mental retardation. They may have extensive skin lesions and internal organs may also be affected. The frequency of neonatal herpes infection in the United States has been estimated at about 500 cases yearly. Furthermore, data suggest that spontaneous abortion in the first trimester and premature delivery in the third trimester are related to herpes infection during pregnancy.

The relative risk of transmission from mother to baby is believed to be related to the amount of virus present in the maternal genital tract at the time of delivery. To prevent infection of babies, laboratory and clinical methods of detecting virus are generally employed in pregnant women with a history of genital herpes. Weekly cultures of the cervix and labia are usually taken during the third trimester, and cesarean sections are performed when indicated, to prevent neonatal exposure during delivery. Between 30 and 50 percent of women with recurrent herpes have cesarean sections. In spite of these precautions, neonatal herpes is increasing.

Dr. Lawrence Corey and Dr. Zane Brown, at the University of Washington at Seattle, have studied the amount of virus shed by pregnant women who had repeated episodes of herpes and by those who had a first episode during pregnancy.

The investigators found that women who had recurrent episodes shed large amounts of virus during recognizable outbreaks, and small amounts when there were no symptoms. These women are usually targeted for pre-labor screening.

Women who developed typical "true primary" infections during early pregnancy responded differently. They had no immunological evidence of prior exposure to herpes simplex virus; in other words, they had no preexisting antibodies to type 1 or type 2 herpes virus. They experienced few or no subsequent episodes of overt disease during the remainder of their pregnancies but, even in the absence of clinical symptoms, shed large amounts of virus. High rates of asymptomatic shedding also occured in women who had a first clinical episode of herpes during pregnancy but who had partial immunity because of previous exposure to type 1 herpes. These initial episodes were not as severe as "true primary" episodes.

Most babies who develop herpes are born to asymptomatic mothers with no previous history of infection. The investigators stress that more preventive measures should be directed toward the small group of women who develop primary infections during pregnancy and who are likely to have asymptomatic recurrences.

Drs. Corey and Brown suggest that routine weekly cultures, which are expensive, might be discontinued in favor of other measures. Instead, they recommend that all women undergo careful examination at onset of labor to detect possible herpes lesions that may have gone unnoticed. Cesarean sections should be performed if suspicious signs of herpes can be recognized

The researchers also suggest that all women, regardless of past history, have cultures of vaginal secretions taken to detect herpes virus at the time of delivery. The cultures will give results within 72 hours, sufficient time to alert parents and pediatricians to the possibility of neonatal infection. If signs of neonatal infection occur, antiviral chemotherapy can be instituted promptly, and these infants can be saved from serious or fatal consequences of infection.

National Eye Institute

It is estimated that one out of every four schoolchildren in the United States has a vision problem. Often, it arises from a refractive error that can be corrected with eyeglasses or contact lenses. But for more than 600,000 children, vision is impaired in ways that make it impossible to achieve correction by these means. Also, for all too many of these children, the impairment cannot be reversed by any known medical or surgical method. Finding more effective ways to diagnose, treat and prevent the disorders that cause visual impairment in childhood is a major goal of the research program of the National Eye Institute (NEI).

One of the major blinding disorders of childhood now receiving attention in the NEI research program is retinopathy of prematurity (ROP). In this disease of premature infants, abnormal blood vessels and fibrous tissue grow on the surface of the retina--the light-sensing tissue of the eye. Severe ROP can end in detachment of the retina and permanent visual impairment. ROP has been increasing in frequency in recent years because of improved survival rates among very small premature infants, who are at particular risk for this eye condition.

In the past year, the NEI has inaugurated a major clinical trial to evaluate cryotherapy as a method of halting the progression of ROP in severely affected infants. In this procedure an instrument called a cryoprobe, which freezes the tissue it touches, is applied to selected sites on the outside of the eyeball. The aim is to alter the underlying retinal tissue so that abnormal blood vessels and fibrous tissue will not grow there; the areas treated by cryotherapy would thus act as a barrier to prevent the spread of the abnormalities that threaten to detach the retina. Although cryotherapy appears promising, its effectiveness and safety have not been fully evaluated. In the new clinical trial, premature babies will be screened for ROP. Those who have potentially sight-threatening ROP will receive cryotherapy in one eye; both eyes will then be observed carefully for signs of progression of the disease.

Dr. Earl Palmer, of the University of Oregon Health Sciences Center in Portland, will chair this study. Data analysis will be coordinated by Dr. Robert Hardy, of the University of Texas Health Sciences Center in Houston. (Twenty-three other medical centers will participate in the study. These participating centers are located in the District of Columbia; Atlanta, Georgia; Baltimore, Maryland; Birmingham, Alabama; Charleston, South Carolina; Chicago, Illinois; Cincinnati and Columbus, Ohio; Dallas, Texas; Detroit, Michigan; Durham, North Carolina; Indianapolis, Indiana; Louisville, Kentucky; Miami, Florida; Nashville, Tennessee; New Orleans, Louisiana; Philadelphia and Pittsburgh, Pennsylvania; Rochester, New York; Sacramento, California; Salt Lake City, Utah; San Antonio, Texas; and

St. Paul, Minnesota.) About 6000 infants of very low birthweight (less than 1250 grams or 2 and 3/4 pounds) will be examined for signs of ROP, and 300 will be enrolled in the cryotherapy trial.

Another childhood eye disorder which is of major importance in the NEI research program is strabismus. In this very common condition, an imbalance of the eye muscles causes one or both eyes to turn inward (cross-eye) or outward (wall-eye). Each year more than 80,000 people undergo eye muscle surgery to correct this disorder. A major problem confronting the surgeon is determining how much correction is required to align the patient's eyes. Because it is difficult to gauge this precisely, many children have to undergo several operations before alignment is achieved.

To evaluate a promising new method that may improve presurgical assessment of children with a common form of strabismus, the NEI issupporting a multicenter clinical trial, headed by Dr. William E. Scott of the University of Iowa in Iowa City.* The trial will determine whether children slated for strabismus surgery are more likely to have a successful outcome if the doctor performs a prism adaptation test before surgery. In this procedure, the child is fitted with a succession of very strong glasses, which contain prisms that bend light in such a way as to encourage the misaligned eye to turn in the proper direction. By determining how strong the prisms must be to achieve this temporary alignment, the doctor obtains an estimate of the amount of surgical correction required to achieve permanent alignment. If such estimates prove to be a useful guide for surgeons, the method may greatly reduce the number of repeat operations required for correction of strabismus.

Among the other genetic and developmental conditions now being studied with NEI support are retinoblastoma (a rare ocular cancer), congenital cataract, amblyopia ("lazy eye"), retinitis pigmentosa (a blinding hereditary disease that strikes children and adolescents), and various refractive errors such as myopia (nearsightedness). This research is expected to yield advances in diagnosis, treatment and prevention that will improve the visual health of American children and, in so doing, spare many adults from the lifelong burden of visual handicaps acquired in childhood.

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* Other centers participating in the prism adaptation study are located in the District of Columbia; Atlanta, Georgia; Baltimore, Maryland; Chicago, Illinois; Los Angeles, California; Miami, Florida; Minneapolis, Minnesota; Philadelphia, Pennsylvania; Rochester, New York; and San Antonio, Texas.

National Institute of Environmental Health Sciences

Research conducted by NIEHS' Intramural Research Program (IRP) in the area of maternal and child health includes studies of: (1) normal and abnormal embryonic development through use of various culture systems along with recombinant DNA techniques and efforts to develop laboratory tests for determining the potential effect of chemicals or drugs on the human embryo or fetus; (2) the effects of prenatal exposure to chemicals on reproductive tract development and function; and (3) the effects of environmental chemicals on preovulatory eggs and spermatozoa.

A system to study the effects of chemicals or drugs on embryos has been developed by NIEHS intramural scientist Dr. Robert M. Pratt and colleagues. This test is based on chemically-induced growth inhibition in a line of cells from the human embryonic palate. There is a good correlation between the amount of drugs and chemicals observed to produce growth inhibition in this cell line and the amount required to produce birth defects, such as cleft palate, in experimental animals. This assay is inexpensive, easy to perform and may help predict which environmental chemicals may cause human birth defects.

NIEHS also supports toxicology research relating to maternal and child health that includes: (1) studies in laboratory animals to determine the potential for chemicals to cause structural and behavioral birth defects in offspring and to generate data on chemicals that pose hazards to pregnant women; (2) development of a system to provide information on an environmental chemical's potential to influence fertility and to affect offspring development by exposure either directly or indirectly before birth or while breastfeeding; (3) analysis of a short-term system for evaluating reproductive toxicants; (4) studying mutation in mouse germ cells; and (5) studying the toxicologic effects of chemicals to identify those capable of inducing heritable germ cell mutations and assessing the human genetic risk of exposure to such chemicals.

Under an NIEHS contract, Drs. Julia George and Catherine Price of the Research Triangle Institute in North Carolina are studying the effects of chemicals on pregnancy and offspring development in mice, rats, or rabbits. These data are often used by the regulatory agencies to estimate the potential risk associated with exposure to a particular compound. Dr. Bernard Schwetz of NIEHS and Dr. Bryan Hardin of the National Institute for Occupational Safety and Health (NIOSH) are managing similar efforts through a contract at Batelle Northwest in Richland, Washington. Another contract of both NIEHS and NIOSH is designed to study chemicals to which people are exposed through the air they breathe. These contracts provide important information about hazards that may lead to infertility or birth defects.

New methods which evaluate the potential for chemicals to cause birth defects in cell culture systems are being investigated at Microbiological Associates in Bethesda, Maryland, under the direction of Dr. Li Yang and at Northrop Services in Research Triangle Park, North Carolina under the direction of Dr. Vernon Steele and Dr. Gene Elmore. Two cell culture systems, one developed at Harvard University by Dr. Andrew Braun and the other at NIEHS by Dr. Robert Pratt, are being used to test about 45 chemicals. The two laboratories are independently collecting data on the systems and the investigators do not know which chemicals they are testing. After three years, the code will be broken to see if the systems are useful. The successful development of such a system may lead to a decrease in the number of whole animal studies required and provide additional information on how chemicals cause birth defects.

Dr. Linda Birnbaum and Dr. James Lamb of NIEHS are studying mixtures of chemicals, particularly contaminants in certain industrial chemicals or those found in hazardous waste sites. Their studies compare the ability of these chemicals to cause birth defects in mice when given alone and the effects of the chemicals in combination. These investigations are important since the general population is exposed to mixtures of chemicals rather than pure isolated chemicals.

Two NIEHS contractors are improving the methods for examining chemical effects on fertility and reproduction in mice. These studies are designed to improve the reliability and decrease the time and cost required to study chemicals for potential reproductive toxicity in animal models.

In a recent study, NIEHS intramural scientists Drs. Donna Baird and Allen Wilcox found that women who smoke cigarettes have significant reductions in fertility. Among 700 women who eventually became pregnant, the monthly chance of pregnancy was reduced almost 30 percent for smokers. The husband's smoking did not affect the couple's fertility.

Dr. Jane Koenig, an NIEHS grantee at the University of Washington in Seattle, is studying adolescents' pulmonary response to inhaling air polluted with sulfur oxides. They are investigating the influence of sulfur dioxide and sulfuric acid in a group of teenagers with allergic asthma and exercise-induced bronchospasm (EIB). These patients inhale the pollutants either through the mouth or through the nose and mouth to determine if the route of entry alters the lung response. To date, the adolescents show large changes in various respiratory measurements following all modes of exposure. Dr. Koenig and her colleagues are also studying another group of allergic asthmatic adolescents who do not have EIB. Preliminary data suggest this group of subjects is much less sensitive to inhaled sulphur dioxide than the asthmatic subjects with bronchospasms.

Chronic lead exposure of children remains a serious environmental concern and a number of research projects have been undertaken to assess lead effects on child health and development. In an NIEHS-funded study on lead effects, Dr. Barry J. Hoffer, at the University of Colorado Health Science Center in Denver, has found that disulfiram--a drug used in the treatment of alcoholism--augments lead transport into the brain. There is a marked hypoexcitability in the brain of disulfiram-treated rats exposed to 0.25 micrograms of lead per liter of drinking water--less than the permissible levels established by NIOSH and the Occupational Safety and Health Administration in their Occupational Health Guidelines--while this same lead level produced no effect in untreated rats. These data highlight the difficulty in establishing "safety levels" for pollutants such as lead, and the need for defining their mechanisms of action.

Division of Research Resources

During the 25 years since its start, the Division of Research Resources' (DRR) General Clinical Research Centers (GCRC) Program has contributed significantly to the improvement of maternal and child health. Currently, 71 of the 78 centers are conducting research into ways to improve the health of mother and child. At the Stanford GCRC in California, researchers proved the effectiveness of a treatment to cure a lung disorder that frequently threatens the lives of newborns who require mechanical respiration. By merely placing his tiny patients on their sides, Dr. David K. Stevenson and his colleagues at Stanford University were able to cure most of the babies who suffer from pulmonary interstitial emphysema (PIE). This disease occurs when air forced into the lung by a mechanical respirator breaks through the organ's air sacs and accumulates in tissues that do not normally contain gases. The escaped air disrupts breathing by damaging the tissues and compressing normal air passages.

Placing the baby on the side with the emphysemic lung reduces air pressure in the damaged lung so it can absorb the accumulated air. The technique is a gentle alternative to invasive methods conventionally used on infants with this problem.

Premature infants are very susceptible to respiratory distress syndrome (RDS), which is the third leading cause of infant death in the United States, according to the National Center for Health Statistics. The syndrome is associated with an inadequate supply of surfactant, which normally coats the inner lining of the lung. Without enough of this substance, the air sacs collapse, forcing the infant to fight for every breath.

At two of DRR's Primate Research Centers, one at the University of Wisconsin in Madison and the other at the University of Washington in Seattle, monkeys are key participants in research aimed at determining the reason for this lack of surfactant and ways to correct the problem.

The course of pregnancy in the rhesus monkey and pig-tailed macaque is remarkably similar to pregnancy in humans, and the onset and course of respiratory distress syndrome is nearly identical, according to Dr. Joseph Kemnitz, a Wisconsin primatologist. The syndrome prevents surfactant from coating the air sacs adequately in the newborns of the two species of monkeys, as it does in human children. In both humans and monkeys, the lungs collapse and appear cloudy or granular in x-rays.

Through basic research, the Wisconsin and Washington investigators hope to obtain a clearer understanding of how normal fetal lungs develop and why they differ from lungs affected by RDS. The Wisconsin team is documenting the course of normal lung development in fetal rhesus monkeys. One objective is to identify the metabolic mechanisms that control the development of lung tissue and production of surfactant. Another is to identify the most effective dosages and timing of dexamethasone administration. Physicians already use this synthetic steroid to stimulate fetal production of surfactant, but results are variable.

In other studies conducted at the Children's Hospital GCRC in Cincinnati, grantees found evidence that Reye syndrome, a potentially fatal disease that afflicts mainly children, may occur much more frequently than national statistics indicate.

The research team estimated the incidence of Reye syndrome during 1981 to be 3.5 cases per 100,000 children living in the Cincinnati metropolitan area. For the same year the Centers for Disease Control estimated the national incidence of the disease to be 0.31 cases per 100,000 children.

Dr. James E. Heubi, assistant director of the GCRC, points out that since the mid-1970's, the Cincinnati area has conducted an intensive Reye syndrome awareness campaign, alerting parents and physicians to early signs of the disorder. As a result, reporting of Reye syndrome in Cincinnati probably is more thorough than nationally. Studies by other researchers support the Cincinnati team's findings that the childhood disease is not as rare as once suspected.

The research indicates that this campaign may have paid high dividends and suggests that early diagnosis and treatment can lead to full recovery for the vast majority of patients. A retrospective analysis done by Dr. Heubi and his colleagues showed that only 5 of 83 children (6 percent) with the mildest form of Reye syndrome progressed to coma. None of the patients died, and only one suffered brain damage.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute of Mental Health

Maternal and Child Health

Conservative estimates have indicated that at least 7.5 million children and adolescents in the United States suffer from mental disorders at any given time. It is important to point out that such an estimate relates to only a part of the problem because those who are affected at a specific temporal point can be expected to represent only a fraction of those who will experience mental illness at some time during the course of their formative years. In addition, many youngsters may suffer from emotional dysfunctions which do not fully qualify as mental disorders. These youngsters, as well as those more seriously affected, can be considered at increased risk for mental illness in adulthood. Indeed, accumulating data suggests that, for many persons, emotional problems early in life are precursors to further difficulties later in the life cycle. All these considerations underscore the importance of directing attention to child and adolescent mental health to alleviate suffering in the young and to strive to prevent problems for both child and adult populations.

The National Institute of Mental Health (NIMH) has been directing resources to the mental health of children and adolescents across the whole range of its programs. These efforts have gone forward in extramural research, intramural research, training, mental health service demonstrations, and in other activities. Some areas of activity and selected developments are outlined below.

EXTRAMURAL RESEARCH

Attention Deficit Disorder/Hyperactivity (ADD/H)

It is estimated that between 3 to 5% of the school-age population suffer from ADD/H. There is evidence that about a third of these children carry some symptoms into early adulthood and beyond. An NIMH-sponsored workshop concluded that core symptoms continue in anywhere from 50 to 80% of samples surveyed when adolescent outcomes are reviewed.

Depression

Studies receiving NIMH support are expected to produce information on screening for depression in adolescents and to provide a very good picture of age patterns of depressive symptoms and disorders and clues to etiology from risk factors and predictors.

Adolescent Suicide

A four year project studying adolescent suicide began January 1984. The investigators are in the early stages of sample selection. They have identified a sample of 73 completed suicides to data. Of these, 63% were between 17 - 19, and the majority were white males. The most frequent methods of suicide were hanging and firearms. Thirty percent had made previous suicide attempts. About 50% of the sample had seen a mental health professional. Although it is too soon to make any judgments about levels of emotional disturbance among young suicides, these early data do suggest a disproportionate number sought help for some problem before killing themselves.

Another project seeks to explore in ethnographic perspective the sociocultural context of adolescent suicide in one Micronesian locale (Truk)--an area with the highest incidence of adolescent suicides and attempts. Ethnographic research techniques and structure method are applied in the study. Specific objectives of the project include: (1) to identify the sociocultural precursors of suicide in this population; (2) to interpret the social meanings of suicide within the adolescent subculture; (3) to elucidate the epidemic dynamics and collective aspects of suicidal behavior; and (4) to further analyze previously collected survey data to identify the syndrome of adolescent suicide.

Autism

Because autism is a low incidence disorder, pairs of twins of whom at least one is autistic do not exist in large numbers.

Dr. Edward R. Ritvo, however, has computerized data on over 350 autistic persons who represent a voluntary sample from across the United States. To date, 61 pairs of twins have enrolled in his study and 40 pairs have met strict research diagnostic criteria for autism. Concordance for autism in these 40 pairs is 95.7% in the monozygotic twins (22 of 23 pairs) and 23.5% in the dizygotic twins (4 of 17 pairs) (American Journal of Psychiatry, January 1985.) This concordance points to a genetic factor in some cases of this disorder.

Children at Risk for Schizophrenia

There is considerable evidence that children born to mentally ill parents represent a population at high statistical risk for psychopathology. Evidence from early family studies, and later twin, adoption, and cross fostering studies lends support to the concept that genetics and environmental interaction is the basis for transmission of schizophrenia. Ten to 12% of the offspring to one schizophrenia parent and 30 to 40% of the offspring of two schizophrenic parents will develop the disorder as compared to about 1% of the general population. On the other hand, about 85% of diagnosed schizophrenics do not have first degree relatives who are schizophrenic. So although potentially useful and important in identifying premorbid indicators of psychopathology, a research strategy that studies children born to schizophrenic parents may be generalizable to roughly 10 to 15% of schizophrenics.

In April 1985, a major conference on Risk Studies in Schizophrenia: Current Status and Future Directions was held in San Francisco with funds from an NIMH grant to the High Risk Consortium. Members of the consortium and distinguished consultants in genetics, biological psychiatry and brain imagery reviewed substantive findings bearing on presumptive risk markers in infancy, early childhood, and adolescence. Parental and intrafamilial factors as risk markers were also discussed. The prediction of intermediate and long-term outcomes for the high risk children was the subject of considerable debate.

Among other issues the group decided that there were certain recurrent trends in the data reported on risk markers for schizophrenia which warrant closer inspection and analysis. This was particularly true for measures of neuropsychological functioning in infancy and early childhood.

Antisocial Behavior

A major prospective longitudinal study, currently underway, is seeking to increase understanding and prediction of such behavior.

High-Risk Studies

Myrna Weissman of Yale is conducting an important study of children at high and low risk for psychiatric disorders and has just completed the first set of data analyses. In a pilot version of this study, based on family history information on the child from the parents, children of depressed probands had a threefold increased risk of any psychiatric diagnosis compared with children of normal probands.

Infant Studies

The Center for Prevention Research is currently funding nine field-based projects designed to investigate the preventive impact of interventions targeted to infants and their families within high risk populations. In combination, these studies are expected to contribute significantly to our understanding of the mechanisms whereby genetic, familial and environmental factors translate prenatal and perinatal vulnerability into mental disorder, and most importantly, the nature, scope, and cost effectiveness of interventions designed to avoid these outcomes.

Impact of Divorce on Children

An NIMH sponsored workshop, drawing on findings from Institute-supported projects, came to a number of conclusions concerning the impact of marital disruption on children.

There was general agreement among the participants that these studies do not indicate gross pathology resulting from divorce; there is, however, some evidence of other behavioral changes associated with divorce. It was agreed that there are some short-term effects of the stress of separation or divorce on many children and these appear to be moderated or influenced by certain process variables within the family and with the child.

The participants noted that up to five years after divorce many families and children have acute psychosocial needs apparently related to the separation. Children from divorced families tend to be absent more frequently, tardy more often, drop out of school, and perform less well academically. In the short term, children display some problems in the area of reduced self-concept, acting out, depression, and anxiety. Over time children in these studies tended to recover in the area of school related functions.

There is evidence that high interpersonal conflict, whether in married or divorced families, is negative for children, and that parenting practices continue to be a major factor in influencing child adjustment pre-during- and post divorce. All too often the child is an unwilling pawn in the spousal conflict, subject to manipulation by one or both parents, and victimized by a series of damaging confrontations that negatively affect adjustment.

Financing Mental Health Care for Children

The Mental Health Economics Research Program issued a special initiative grant announcement to stimulate research on a variety of mental health reimbursement issues and provided technical assistance to potential grantees who are interested in examining reimbursement issues impacting on the financing of care for children.

INTRAMURAL RESEARCH

Studies of Children of Depressed Parents and Well Parents

Summaries of some findings of individual studies are outlined below. Findings are preliminary in most instances. Also, findings being reported are mainly on the younger children; later analyses will include the older siblings. Emphasis in the preliminary reports is on group comparisons in terms of the diagnosis of the mother.

Children of depressed mothers receive more negative attributions than do children of well mothers. Moreover, many more mixed messages (positive comments with negative comments) are given to children of depressed mothers, but providing uncertain and possibly anxiety-provoking information about the self.

Depressed mothers are more critical of their children, particularly in affective aspects, than are normal mothers.

An attentional deficit in children of mothers with depression is suggested. There is a significant difference in time spent on different play objects by children of the depressed and normal groups. Children of mothers with a diagnosis of major depression tend more to move from object to object, developing less sustained involvements than do the children of well mothers.

Comparisons between normal mothers and mothers with major depression indicate that children of depressed mothers have more problems of noncompliance than children of normal mothers, that depressed mothers are relatively ineffective in controlling their children's behavior and that this difficulty increases with the child's age. Much more analytic work lies ahead in terms of understanding these interactions.

Anger, sadness, and low negative mood were expressed least frequently by well mothers, and most frequently by major depressed mothers. Positive affect was expressed most frequently by well mothers and least frequently by bipolar mothers.

Diagnosis in Child Psychiatry

A case history exchange was carried out to study the diagnosis of hyperkinesis (attention deficit disorder) and conduct disorder in Europe and the United States. Research teams at the National Institute of Mental Health and the

Maudsley Hospital in London, as well as clinician teams in Washington, D.C. and London, rated 40 case histories, 20 with videotapes. Both the International Classification of Disease - 9th edition (ICD-9) and Diagnostic and Statistical Manual (DSM III) were used by all raters.

Preliminary data analysis shows that much of the wide discrepancy between European and U.S. rates is due to the different schemes involved. ICD-9 only permits one diagnosis, and conduct disorder is so defined as to be quite inclusive. Thus, the research teams agreed well within schemes; both diagnosed conduct disorder more frequently using DMS III, which permits multiple diagnosis. Agreement was good between research teams within each scheme.

Preliminary analyses of the clinician team data show both influence of diagnostic schemes as well as an influence of the nationality of the clinician. While still diagnosing attention deficit disorder more frequently using DSM III, British clinicians also implement the schemes differently.

In general, childhood hyperkinesis has been considered an American phenomenon and widely ascribed to dietary, cultural and/or environmental factors. The present study suggests that the children do not differ so widely as had been supposed and that most of the difference is accounted for by clinician rating scheme and possibly referral differences in the two countries.

TRAINING

NIMH has been working to develop new child- and youth-focused researchers in the biological sciences, behavioral sciences, and clinical sciences. The Institute has supported both institutional training programs and individual fellowship awards under the National Research Service Act authority. Newly supported institutional grants relating to children, youth, and their families have included programs concerned with the following: human development and family studies, child neuro-psychiatric problems, family processes and psychopathology.

Clinical training projects related to children and youth are being supported for psychiatry, psychology, social work, psychiatric nursing, and multidisciplinary programs. Over 100 new and continuing projects were supported in FY 1985.

In State human resource development, NIMH, in an ongoing collaboration with the National Institute of Handicapped Research, Department of Education, funded eight States (Alabama, Colorado, Florida, Idaho, Kansas, Maryland, Vermont, and Washington) in 1984 for the purpose of improving the accessibility of mental health services to emotionally disturbed children through their public education system.

MENTAL HEALTH SERVICE DEMONSTRATIONS

In 1984 Congress earmarked $1.5 million to develop a new initiative to improve service delivery for severely emotionally disturbed children and adolescents. From this congressional mandate to develop new service delivery systems, the National Institute of Mental Health developed the Child and Adolescent Service

System Program (CASSP), within what is now known as the Division of Education and Service System Liaison. With a second year appropriation of $3.9 million, CASSP has grown into a program that, through its grant activities, impacts the seriously emotionally disturbed (SED) children and adolescents of nearly half the States in the country; and, through its technical assistance program, its impact is on the whole country and the 3 million SED youngsters.

The major goals of CASSP are:

- Improve the availability of continuums of care for severely emotionally disturbed children and adolescents, and thus improve the availability and access to appropriate services across child service systems
- Develop leadership capacity and increase priority in allocations of resources for child and adolescent mental health services
- Establish coordination mechanisms and thereby increase levels of collaboration, and ultimately efficiency of service delivery, among agencies
- Develop the capacity for, and provide technical assistance on child and adolescent service system development
- Evaluate the principles and practices of CASSP

The grant program currently funds 22 State grants. These grants support the creating of State-level foci for severely emotionally disturbed children and adolescents (under the auspices of the child mental health authority.) All component agencies, public and private, are called upon to become part of a coalition to assure the appropriate provision of services. These agencies include on a State-level: mental health, health, education, welfare and juvenile justice. Alternative youth services and local service advocacy groups must also be included as equal partners in this coalition. Once a State has developed comprehensive system building on a State level, CASSP promotes the translation of these systems to the community level.

The CASSP technical assistance and research program consists of three major components. These include:

(1) the development and publication of technical assistance resources and materials;

(2) knowledge dissemination and exchange; and

(3) work with other agencies at the Federal and State level, and other national organizations (including professional, parent, and citizen groups) concerned with improving services for severely emotionally disturbed children and adolescents.

The NIMH FY 85 funds were used to provide technical assistance to funded CASSP States, to begin planning for several regional training and knowledge dissemination conferences for both funded CASSP States and unfunded States, and to conduct a number of knowledge-gathering and dissemination activities, including several short-term studies.

OTHER ACTIVITIES

Many other kinds of activities in addition to the types exemplified above have been carried out by NIMH regarding children and youth. A number of these relate to communications and education. For instance, a TV information packet on adolescence and depression was published and distributed, and is now being reprinted to fill the many requests for it. Another example is a videodisc curriculum on adolescent suicide. The optical disc/computer interactive curriculum will be for use by third and fourth year medical students. Working with the National Library of Medicine, the contractor and an expert advisory panel have completed all planning for content and format, scriptwriting and videotaping. The curriculum will be pretested in January 1986.

Numerous NIMH activities related to children and youth are carried out in collaboration with other agencies. During FY 1985 there were many such efforts; the following are some examples: an interagency study on financing long-term care for children, a DRG study that included special attention to children and youth, a reformulation of mental health disability criteria for children and youth, a multi-agency effort that led to a National Strategy Conference on Mental Retardation and Mental Health.

Mental Retardation

Obligations

	1983	1984	1985	1986 Appropriation	1986 Available after sequestering	1986 Revised estimate	1987 Estimate
National Institutes of Health:							
National Institute of Child Health and Human Development....	$32,496,000	$32,579,000	$39,859,000	$41,000,000	$39,200,000	$39,100,000	$39,100,000
National Institute of Neurological & Communicative Disorders and Stroke...........	7,896,000	7,542,000	11,124,000	12,168,000	11,645,000	11,377,000	11,256,000
National Institute of Allergy and Infectious Diseases..	10,810,000	10,561,000	12,728,000	13,171,000	12,602,000	12,535,000	12,130,000
TOTAL, NIH.........	51,202,000	50,682,000	63,711,000	66,339,000	63,447,000	63,012,000	62,486,000
Centers for Disease Control:							
Immunization Program..	39,253,000	42,068,000	54,142,000	59,594,000	57,032,000	57,032,000	56,012,000
Lead-Based Paint Poisoning Prevention Program..............	533,000	533,000	533,000	533,000	510,000	510,000	533,000
TOTAL, CDC.........	39,786,000	42,601,000	54,675,000	60,127,000	57,542,000	57,542,000	56,545,000
TOTAL, PHS.........	90,988,000	93,283,000	118,386,000	126,466,000	120,989,000	120,554,000	119,031,000
Social Security Administration:							
Estimated payments, benefits from RSI-DI trust funds...........	1,175,000,000	1,250,000,000	1,300,000,000	1,350,000,000	1,350,000,000	1,350,000,000	1,400,000,000

Estimated general fund payments for supplemental security income.......	1,045,000,000 1/	1,006,000,000 1/	1,183,000,000	1,282,000,000	1,282,000,000	1,282,000,000	1,391,000,000
TOTAL, SSA.........	2,220,000,000	2,256,000,000	2,483,000,000	2,632,000,000	2,632,000,000	2,632,000,000	2,791,000,000
Health Care Financing Administration.........	2,334,000,000	2,448,000,000	2,682,000,000	2,928,000,000	2,928,000,000	2,928,000,000	3,105,000,000
TOTAL DHHS.........	4,644,988,000	4,797,283,000	5,283,386,000	5,686,466,000	5,680,989,000	5,680,554,000	6,015,031,000

1/ Due to federal legislation mandating check payment on a banking day, the SSI program made 13 monthly payments in FY 1983 and 11 payments in FY 1984.

NATIONAL INSTITUTES OF HEALTH

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

MENTAL RETARDATION

Mental retardation is one of the most complex and challenging problems related to human development. Mentally retarded people suffer from mild to profound intellectual deficiences, impaired learning capabilities, and difficulty adapting their behavior to society. Mental retardation weighs heavily on the individual, his family, the community, and the economy and resources of the nation.

In the United States, there are 6,900,000 mildly retarded people and 700,000 moderately to profoundly retarded ones. Social, educational, and economic factors play an important causative role in mild retardation. Biological factors such as genetic defects, prematurity, infection, or injury at birth or in early childhood cause much of the more serious retardation.

The National Institute of Child Health and Human Development (NICHD) is the main federal agency for research into the causes, treatments, and prevention of mental retardation. While NICHD intramural scientists conduct some studies on mental retardation, other scientists conduct the bulk of the research in medical centers, universities, and at twelve Mental Retardation Research Centers (MRRC) suppported by the NICHD. At these facilities, NICHD grantees and contractors provide major contributions to our knowledge of these disabling conditions.

Down syndrome (trisomy 21) is the most common and readily identifiable genetic condition among the mentally retarded. A woman's risk of bearing a child with Down syndrome increases dramatically with advancing age. NICHD is investigating reasons for this association.

One hypothesis concerns the age of the mother's egg cells or oocytes. The entire complement of oocytes in a human female is formed well before birth and stored in the ovaries. Thus, oocytes are vulnerable to noxious agents that a woman may be exposed to throughout her life. Another influence may be that older mothers are not as likely as younger mothers to spontaneously abort chromosomally abnormal conceptuses and are therefore more likely to bear a child with Down syndrome.

The primary genetic abnormality of Down syndrome occurs on chromosome 21. Genes, segments of the DNA molecule containing the code for a specific function, are located on the chromosomes. Investigators have mapped eight specific genes on chromosome 21. Close genetic correspondence to this human chromosome has been demonstrated in an animal model--on mouse chromosome 16.

NICHD grantee Dr. Charles J. Epstein and investigators at the MRRC at the University of California, San Francisco, recently succeeded in mapping four genes on chromosome 16 in the mouse that correspond to genes located on human chromosome 21.

The mechanisms by which chromosomal abnormalities develop in mice and humans are similar, so Dr. Epstein's research is promising. By using an animal model to study Down syndrome, researchers can continue to explore how developmental abnormalities occur, especially during organ formation; the effects of genetic and environmental factors on the expression of chromosomal abnormalities; and can test new treatments for the disease.

In other research, Dr. David Kurnit and colleagues at Boston Children's Hospital Medical Center have found that cells from the lung and heart of fetuses with Down syndrome are more adhesive than normal cells. Using anatomic studies and computer simulations, they demonstrated that the increased adhesiveness might interfere with proper organ formation.

Phenylketonuria (PKU) is an inherited metabolic disorder. People with PKU lack an enzyme necessary for metabolism of phenylalanine, an amino acid essential for normal growth and development. Untreated people generally suffer from severe mental retardation, behavioral problems and epilepsy, and many require life-long institutional care.

Screening programs for PKU, begun in the 1960's, have successfully diagnosed most infants with PKU within a few weeks of birth. Such infants are given a diet low in phenylalanine, and this reduces or prevents severe handicaps. They remain genetically affected,however.

The early screening and treatment programs of the past 20 years have resulted in a population of females who have developed normally but who nevertheless have PKU, and who are now reaching or approaching the childbearing years. Women with PKU who are maintained on a regular diet during pregnancy are at high risk of bearing a child suffering from mental retardation or other congenital problems. In addition, information gained from animal studies shows that a level of phenylalanine that is safe for the mother may be unsafe for the developing fetus.

Therefore, NICHD has begun a collaborative project, coordinated by Dr. Richard Koch of Children's Hospital of Los Angeles, California, involving women from the 50 states, the Districtof Columbia and Canada, to evaluate the usefulness of phenylalanine-restricted diets in reducing problems associated with maternal PKU. This cooperative U.S.-Canadian longitudinal study seeks to determine the optimal diet in terms of phenylalanine level, timing, and efficacy.

In other research, NICHD-supported investigator Dr. Savio

L. C. Woo at Baylor College of Medicine in Houston, Texas, has located the defective gene responsible for PKU--phenylalanine hydroxylase (PAH)--on human chromosome 12. Using recombinant DNA technology, Dr. Woo and his colleagues have developed prenatal diagnostic techniques that can predict for about 90 percent of families with a history of PKU whether a fetus has the disease.

Gene therapy involves replacing a defective gene with a normal, functioning gene. Advances in biotechnology now make it theoretically possible to apply gene therapy in a number of lethal genetic disorders. Studies, mostly on rodents, have shown that gene transfer can be performed.

A research team headed by grantee Dr. Savio L.C. Woo cloned and inserted a copy of human PAH into a special strain of mouse cells. The transformed cells performed in a way characteristic of certain cells in humans who have PKU. This research suggests that alternative therapies for PKU patients may someday be feasible by gene therapy.

No effective therapy is currently available for several other genetic diseases, making them good targets for attempts at gene therapy. Lesch-Nyhan syndrome, one such disorder, is characterized by mental retardation and early death. NICHD is funding a study conducted by Dr. Theodore Friedmann at the University of California, San Diego, to develop gene transfer methods for treatment of Lesch-Nyhan syndrome.

The mature nervous system contains a huge number of nerve cells, all of which make specific connections. The NICHD is studying how these connections become established during development of the embryo and fetus. Intramural scientist Dr. Douglas Brenneman and colleagues are seeking clues to interactions between nerve cells and cells in the connective tissue that supports nervous tissue. They have shown that interaction during a critical period of nervous system development is influenced by the compounds that are known as pedptides.

Neural tube defects are the most frequent and severe nervous system malformations. Such defects often cause death before or soon after birth. Of babies with neural tube defects who do survive the first 24 hours, 20 percent suffer from moderate or severe mental retardation, according to NICHD-supported studies.

Formation of the neural tube occurs early in development. During the first weeks of gestation, a structure called the neural plate is the foundation of the developing central nervous system, including the brain and spinal cord. The "plate" folds to form the "tube." If the neural tube fails to close by a specific time during embryonic development, abnormalities of the brain or spinal cord occur.

The incidence of neural tube defects varies over time and between populations. This variation is apparently attributable to environmental influences. Intramural scientist Dr. Harold Gainer is focusing research on aspects of central nervous system development which, if affected by toxic substances, lead the defects.

In another study, NICHD grantees in Illinois and California have begun a large-scale trial to study the association between vitamin use and neural tube defects. Recent reports from Great Britain have suggested that vitamin supplementation for women around the time they conceive may prevent neural tube defects. The supplement used is folate, a B-vitamin.

Dr. Joe Leigh Simpson at Northwestern University Medical School in Chicago and Dr. George Cunningham at the California Public Health Foundation in Berkeley, are studying whether women who bear infants with neural tube defects were less likely to use vitamins than women who did bear such infants. If this new, larger study does reveal a link, it will show that many of these birth defects might be preventable.

Fetal alcohol syndrome (FAS) is a cluster of defects that appears in some babies born to women who drink heavily during pregnancy. The babies may have grown slowly before birth and commonly suffer from growth problems after birth as well as impairments of the central nervous system. Abnormalities of the head and face, limb and heart malformations, and mental retardation are common in severe cases.

When a mother consumes alcohol, it readily crosses the placenta to the fetus. Because substances for metabolizing alcohol are not present in the embryo, and barely present in the fetus, high amounts of the alcohol stay in the fetal tissue for a longer period of time. Some research suggests that this may cause problems with cell growth and tissue formation, especially during critical periods of fetal development.

The public health implications of fetal alcohol exposure are considerable. Severe alcoholism among pregnant women is estimated at 0.42 to 1.25 cases per 1,000 pregnancies. But lighter drinking is far more common.

Recent studies by NICHD grantee Dr. Ann Streissguth and her colleagues at the MRRC at the University of Washington, Seattle, have found that mild and moderate drinking during pregnancy may also have damaging effects to the fetus. This is known as fetal alcohol exposure (FAE).

Partial expression of the FAS disorder can reasonably be expected in the children of women who drink but are not alcoholics. There is no threshold level of consumption below which problems fail to occur, but the more alcohol consumed, the more likely that the fetus will suffer severe problems.

The probability of developing FAS appears to be affected by genetic factors. Only 33 percent of alcoholic mothers give birth to FAS babies, and cases exist in which only one of a set of fraternal twins was afflicted.

Intramural scientist Dr. Anil Mukherjee has established in studies with rats that thiamine deficiency in the mother can lead to growth retardation before birth. Dr. Mukherjee used rats that were more susceptible to thiamine deficiency than others to gain information on predisposing genetic factors in humans.

Dr. Mukherjee found that growth-retarded rat pups born to thiamine-deficient mothers remained smaller than others after being born and were significantly poorer learners. These data suggest that postnatal growth retardation and poor learning ability, characteristic features of FAS, may be related to thiamine deficiency in pregnant women.

Other NICHD studies on FAS suggest that malnutrition may also play a role. Dr. Mukherjee's studies suggest that lack of oxygen and disturbance of the acid-balance in the fetus contribute to maldevelopment. It has also been speculated that alcohol may kill cells, disorganize tissue structure, and suppress the release of growth hormone. Research into the causes of this problem continues.

The effects of prenatal protein deficiency on brain development are being studied by an NICHD-supported team of investigators headed By Dr. Oscar Resnick at the Worcester Foundation. Because the phases of development in the rat brain are easily correlated with phases of human brain development, the researchers are using this animal model to study effects on brain development.

They have found that irreversible neurological, physiological, and behavioral changes occur in rats who suffered only a mild protein deficiency before birth. These changes occurred even though the mothers had a normal weight gain during gestation and the pups had normal birth weight and postnatal growth. This suggests that human infants with adequate birth weight, head circumference, and growth rate may still be at risk of developmental disorders if prenatal protein intake was insufficient.

Studies are under way on new approaches to analyzing the blood of women at high reproductive risk, such as those who have had more than one spontaneous abortion. When NICHD researcher Dr. Gene P. Sackett and colleagues at the University of Washington MRRC in Seattle used monkey serum as a culture on which rat embryos fed, they discovered that the embryos reacted differently to serum samples from high-risk monkeys than to serum from monkeys with excellent reproductive histories. Research is now being conducted on the factors in the blood of the high-risk group that cause embryo reactions. Antibodies to certain proteins have been identified as strong antifetal substances.

In another research project supported by NICHD, Dr. Sackett is using a colony of pigtail monkeys to gain information on genetic, prenatal, perinatal, and postnatal factors that result in death, premature birth, and delayed or retarded development. Important information was found in the areas of social development and recognition memory. Monkeys born to mothers who had been exposed to stress while pregnant showed little interest in other young monkeys and did not exhibit the normal interest in novel stimuli. Moreover, they appeared to have a basic deficit in processing information, being unable to compare information at one time with that gained at another.

Amniocentesis has been shown to be a safe and accurate test to determine if a fetus has inherited a genetic disease. Chorionic villus sampling is a new method of prenatal diagnosis which involves analysis of the outermost membrane that surrounds the fetus. Biochemical and genetic tests are performed on cells taken from the membrane. Chorionic villus sampling can be performed between the 8th and 11th week of pregnancy, thus it yields results 1 to 2 months earlier than amniocentesis.

Through a cooperative agreement with seven medical centers, NICHD has initiated a study comparing the safety and accuracy of chorionic villus sampling with amniocentesis. It is expected that several thousand women seeking prenatal diagnosis will enroll in the study. The pregnancies will be followed, and newborn infants will be examined.

Exposure to lead can cause mental retardation ranging in severity from mild to profound. However, new research suggests that lead-caused retardation may sometimes be reversible. Two research teams, one headed by NICHD grantee Dr. Stephen Schroeder at the MRRC at the University of North Carolina, Chapel Hill, and the other directed by Dr. Alan Leviton at the Boston Children's Hospital Medical Center, are studying the relationship between lead exposure and children's IQ. They initially found a strong relationship between the two, but by the end of the 5-year study, it was no longer statistically significant.

Difficulty in learning and performing cognitive tasks is the hallmark of mental retardation. For this reason, educational research has been a focus of those interested in treating or preventing the problem.

Dr. Craig Ramey, an NICHD grantee at the University of North Carolina at Chapel Hill, examined the influence of intense early childhood education on mental development. High-risk children were randomly assigned at birth to a control group, or to a group in which the children received either family education or educational day care.

Standardized tests of mental development at 3 years showed higher scores for the group with more intense education, while the other groups' scores had declined. These results indicate that intense early educational intervention may prevent intellectual decline in children at risk of mental retardation.

New techniques may revolutionize the way in which retarded children and adults learn information necessary for practical skills. In an NICHD research program headed by Dr. Lawrence Stoddard, a grantee at the Eunice Kennedy Shriver MRRC in Waltham, Massachusetts, retarded children are being taught a learning technique in which they gain new information by ruling out alternatives that they already know. The technique, often taught to older normal children as a test-taking strategy, is being used even with severely retarded people for teaching such skills as handling money. Though the retarded sometimes take a while to respond to the new learning situation, they pick up new information rapidly once accustomed to the structure of the task and learn to generalize a few examples to many combinations of facts.

It has been suggested that one barrier to mainstreaming retarded children into regular classrooms is that they are often disruptive. However, a study conducted by NICHD grantee Dr. Steven Forness at the University of California at Los Angeles MRRC, involving 646 retarded children in 50 classrooms, revealed that less than 9 percent were seriously disruptive.

Language delay is often the first sign that a child is mentally retarded. Research is under way in several of NICHD's MRRCs to gain information on the development of language skills among normal infants. Such studies provide baseline data against which to compare the performance of infants suspected to be retarded.

Another interest is in conversation skills as an index of language competence. A recent study conducted by Dr. Jon Miller and his colleagues at the Waisman Center on Mental Retardation and Human Development, University of Wisconsin, of Down syndrome adolescents suggests that language skills go hand in hand with communicative competence in these individuals. These results contradict the view that language skills deteriorate with age in Down syndrome. The researchers also found that Down syndrome adolescents were able to speak with more competence as they assumed more speaking roles, adjusting their level of language to take charge of the conversation.

Early identification of children at risk of mental retardation and developmental disabilities is important so that these children can receive the best care and education possible. NICHD grantee Dr. Susan Harris, at the University of Washington MRRC in Seattle, has recently developed a new assessment tool to identify developmental handicaps in infants. This tool, the Movement Assessment Index, will contribute to both research and clinical practice of early screening.

Dr. J.D. McKinney, an NICHD-grantee at the University of North Carolina, Chapel Hill, and his colleagues have followed a large group of learning disabled children for a number of years. They are working on a classification scheme to identify subgroups of the learning disabled. Such clustering might allow educational intervention tailored to needs and would also be applicable to mentally retarded children in special education classes.

Among the most exciting research is that concerning relationships between behavior and physiological systems. One research team, headed by Dr. Frank Duffy at the MRRC, Children's Hospital, Boston, gains information on the brain's electrical activity among newborns and links it with information on the babies' behavior at ages 9 and 18 months. The researchers have been comparing premature and normal babies and have identified four clusters of infants, varying in brain organization and reactivity. These results suggest that certain areas of the premature baby's brain may become overstimulated by the world outside the uterus.

Another research team directed by Dr. Gary Galbraith at the University of California at Los Angeles MRRC is studying the decrease in performance that occurs when people try to do two things at once. Retarded people have more problems with simultaneous activity than normal people. Since one of the tasks studied was speaking, it appears that retarded people have poor dominance in the area of the brain that controls speech. Using machines that measure brain activity, the researchers link certain tasks to specific brain processes.

Lately, researchers have focused attention on retarded adolescents to gain insights into this often neglected period of development. The adjustments accompanying adolescence, trying in almost all teenagers, appear to be acute among the retarded.

Dr. William Reynolds at the Waisman Center on Mental Retardation and Human Development, University of Wisconsin, has developed a number of instruments to study personality. In a recent study, educable mentally retarded youngsters were examined according to two new scales--one measuring depression, another measuring "learned helplessness," or the feeling that one's life is not personally directed but instead responds to unpleasant uncontrollable events. Retarded adolescents showed more depression and learned helplessness than nonretarded teenagers did. Researchers point out that a feeling of helplessness among retarded adolescents is fairly realistic. On the other hand, the study indicates that special attention should be given to them.

Findings from another project show that retarded teenagers significantly influence their home environment. A study conducted by NICHD grantees Drs. K. Nihira, Iris Mink, and C. Edward Meyers at the University of California at Los Angeles MRRC, found that retarded youngsters' adjustment, social competence, and self-competence brought on changes at home. This means that retarded children are not passive recipients of parental influence; they are active partners in constructing the environment that shapes their social and cognitive development.

Drs. Andrea Zetlin and James Turner at the University of California at Los Angeles, studied the transition from adolescence to adulthood among the mentally retarded. Retarded youths and their parents provided information about their lives over a number of years. The researchers found that many of the problems of adolescence disappeared with adulthood. Normative achievement was identified as the most significant contributor to a feeling of self-identity and well-being.

Most mentally retarded children now grow up at home instead of being institutionalized, as in the past. This trend has stimulated expansion of research and development of new methods to study the family process.

Dr. Kathyrn Barnard and her research group at the MRRC, University of Washington, Seattle, have developed a method for measuring mother-infant interactions. The new method has been shown to be useful in identifying problem relationships. Researchers expect that it will help in studying handicapped infants and their mothers.

Institutions for the mentally retarded are changing. Increasingly, legislation and lawsuits challenge the usefulness of such institutions and more retarded people remain in the community. Analyses done by Dr. Richard Eyman at the University of California at Los Angeles, show that the population in institutions is changing to a residual one of older, profoundly retarded people who have organic diagnoses and severe behavior problems. Studies such as this are important to evaluate the services institutions need to provide and the changes occurring in communities where, more than before, retarded persons live.

National Institute of Neurological and Communicative Disorders and Stroke

Mental retardation research supported by the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) focuses on disorders that damage the developing brain during the perinatal period and early childhood. The goals of NINCDS-funded studies are to understand how the brain and nervous system develop normally, identify what goes wrong in developmental disorders, find ways to treat the resulting problems, and ultimately, prevent abnormal development.

At the University of California at Los Angeles, NINCDS grantee Dr. Claude Wasterlain is investigating the relationship between seizures in newborns and mental retardation. The issue of whether seizures in newborns damage the developing brain continues to be controversial. In the normal brain, the areas of greatest activity have been shown to have the most cerebral blood flow and the highest rates of metabolism. But this year, in observing newborn rats, rabbits and monkeys during seizures, Dr. Wasterlain found this association was not consistent: he noted that the most active areas of these animals' brains were not always the sites of greatest cerebral blood flow or highest rates of metabolism. This observation could explain how seizures might contribute to brain damage and may provide a scientific basis for developing treatments to control or eliminate such seizures.

Dr. Aubrey Milunsky, an NINCDS grantee at Boston University in Massachusetts, heads a research team investigating possible causes of mental retardation, birth defects, and genetic disorders. To date, more than 4,000 of the intended 27,500 pregnant women undergoing genetic amniocentesis have been enrolled in the team's current study. The research group will examine the results of amniocentesis procedures and blood tests, analyze toenail clippings for trace elements such as iron, calcium, and potassium, and correlate information from patient interviews. Questionnaires have been specially designed to collect information from study participants before, shortly after, and 1 year after giving birth. A goal of this study is to produce new knowledge about the causes of neural tube defects and other congenital defects that may result in mental retardation.

NINCDS intramural scientist Dr. John Barranger directs a research team studying neurogenetic disorders that affect the nervous system and cause mental retardation. Building on their previous isolation and cloning of the gene for Gaucher's disease, these investigators are working to identify the genes responsible for four other genetic disorders: metachromatic leukodystrophy, Nieman-Pick disease, Fabry's disease, and mucopolysaccharidosis, type 1. The ultimate goal of this work is to develop therapies which would allow patients with enzyme deficiencies to synthesize effective enzymes.

National Institute of Allergy and Infectious Diseases

Pregnant women who become infected with some types of viruses, parasites, or bacteria may transmit the infection to their unborn or newborn baby. In many cases, infections before or at about the time of birth have no effect, but in other instances these infections may result in death or serious permanent impairment such as mental retardation. Research supported by the National Institute of Allergy and Infectious Diseases (NIAID) is directed towards finding better ways to prevent and treat infections that can occur during pregnancy and severely affect the health and well-being of infants and children.

The most important cause of congenital viral infection is cytomegalovirus (CMV), which affects about one to two percent of babies born in the United States. CMV can be transmitted from mother to baby before birth, during birth via the genital tract, or after birth through breast milk. The majority of active CMV infections in pregnant women are recurrent asymptomatic infections, and these recurrences cause most of the congenital infections. Although CMV-infected infants and adults usually show no symptoms, about one of every ten infected babies is born with symptoms such as jaundice, enlarged liver and spleen, and brain abnormalities.

At the University of Washington School of Medicine, NIAID grantee Dr. King K. Holmes and his colleagues are studying the prevalence of CMV infection in pregnant women to try to determine who is at risk for primary (first) or recurrent CMV infection during pregnancy. Dr. Holmes found that women in the first group were more likely to have been born in North America, to have had fewer venereal infections, and to have had fewer pregnancies than were women with recurrent infection.

Patients in the study were also tested to see if they shed virus in the cervix--the neck of the uterus, which leads to the vagina. Shedding would cause an increased risk for transmission of the virus during birth. Higher rates of viral shedding were associated with younger age, the third trimester of first pregnancy, presence of chlamydial infection, and race other than white or black. Racial factors have been noted in other studies from countries such as Japan, where a significantly higher rate of shedding in the cervix occurs during pregnancy compared with non-Asian women in the United States. Dr. Holmes' study suggests that an explanation may be that female infants infected during birth have a greater likelihood of experiencing recurrent CMV infection when they grow up and become pregnant themselves.

Another common but potentially devastating infection of the embryo or fetus is toxoplasmosis, a disease caused by a parasite. Toxoplasmosis is transmitted by the feces of an infected cat or through uncooked or undercooked meat. Like CMV infection, toxoplasmosis causes few if any symptoms in adults and may not cause symptoms in a congenitally infected infant at birth. However, several months to years later, the child may develop blindness, epilepsy, mental retardation, and other severe disorders. These consequences can often be avoided, however, if treatment is started promptly after birth.

NIAID grantee Dr. Jack S. Remington, at the Palo Alto Medical Research Foundation, has found a technique--called "protein blotting"--for studying and diagnosing congenital infections such as toxoplasmosis in the newborn. Antibodies in a sample of an infected baby's blood react with antigens or markers of the toxoplasmosis parasite, and produce characteristic bands. The bands do not appear in blood samples from the babies' mothers. Nor are they present in the blood samples of babies not infected with the parasite. This technique can help identify newborns in need of treatment.

Dr. Remington studied five families in which more than one person had toxoplasmosis. He found that cats were implicated in four of the families. Oocysts, the form of the parasite that is shed in cat feces and that can infect humans, can live for long periods. The findings suggest that when a patient is diagnosed with toxoplasmosis, pregnant women in the family should also be tested.

Group B streptococci (GBS) infection is the most common fatal bacterial infection in the newborn, causing several thousand infant deaths each year, particularly among premature infants. As many as half of babies surviving GBS can suffer blindness, deafness, cerebral palsy and mental retardation. GBS can be transmitted to babies at birth if their mothers harbor the bacteria in the genital tract. The mothers have no symptoms of GBS infection and some women do not produce antibodies that would protect their infants.

NIAID-supported scientists are developing a vaccine for pregnant women who lack the antibodies. Some women do not seem to produce the antibodies even after immunization. Researchers are investigating the use of immune serum globulin, a blood product containing the antibodies, during pregnancy to make the fetus immune.

Dr. Kwang Sik Kim, an NIAID grantee at Harbor-UCLA Medical Center in Torrance, California, has developed a rat model of human newborn GBS infection, in which infection is acquired orally, as it is thought to be in humans. After taking the bacteria orally, the animals had GBS established in their gastrointestinal tracts and in many cases had a systemic disease that was similar to GBS disease in newborns.

When Dr. Kim gave the immune serum globulin by mouth to animals who had received the bacteria, they developed significantly lower rates of GBS gastrointestinal colonization and systemic disease than control animals did. NIAID grantee Dr. Carol Baker, Baylor College of Medicine in Houston, has found that the globulin contains substantial amounts of GBS antibodies that have antibactericidal activity in neonatal blood.

Centers for Disease Control
Immunization
Mental Retardation

A rubella epidemic occurred in the United States in 1964-65 and resulted in an estimated 30,000 cases of congenital rubella syndrome (severe birth defects) and left nearly 15,000 babies mentally retarded, deaf, or blind. In 1970 when a rubella vaccine became available for use, the Centers for Disease Control provided project grants and technical assistance to State and local health agencies to support an intensive rubella immunization program. In 1970, 56,552 rubella cases were reported and 31 deaths occurred.

One of the program goals of the Immunization Initiative, which began in 1977, was to raise immunization levels of children under age 15 against rubella to at least 90 percent by October 1, 1979. This goal was exceeded by that date, and the rubella level is presently 98 percent, as indicated by the review of school-enterers immunization records during the 1983-84 school year.

Reduction of disease morbidity is the ultimate goal. A new record low occurred in 1985 with only 604* rubella cases reported. There were no cases of congenital rubella syndrome reported during this time period.*

Appropriate administration of safe and effective vaccines remains the most cost-effective method of preventing human suffering and reducing economic costs resulting from vaccine-preventable diseases. Since 1963, the Centers for Disease Control has provided project grant support to assist State and local health agencies in planning, developing, and conducting childhood immunization programs. The funding for FY 1985 was 42.4 million.

Benefit-cost analysis of immunizations demonstrates high rates of return and indicates that immunization programs make an important contribution to health sector cost containment efforts as well as to the quality of life of the communities served. For example, it is estimated that measles immunization currently saves approximately $500 million per year, and that polio immunization saves about $1 billion per year. Over 59 million cases of measles and 19,500 cases of mental retardation have been averted, and 5,900 children's lives have been saved because of measles immunization.

State and local immunization programs, supported by these funds and other Federal resources, have raised immunization levels higher than ever before, and reduced the reported occurrence of most vaccine-preventable diseases to the lowest levels ever, or to near record lows. The following data describe the latest immunization levels and reported disease incidence:

*Provisional data

	Immunization Levels (National Weighted Results)		Reported Cases	
Disease	1983-84 School Year	1984-85 School Year	1984	1985*
Measles	98%	98%	2,587**	2,704
Rubella	98%	98%	752**	604**
Polio	97%	98%	8	5**
Diphtheria	97%	97%	1**	2
Tetanus	97%	97%	74	71**
Pertussis	97%	97%	2,276	3,275
Mumps	97%	98%	3,021**	2,886**

*Provisional Data
**Record low

With the attainment of these immunization levels, major epidemics of these diseases have been eliminated and the backlog of underimmunized school-age children has been virtually eliminated. In addition, grant resources support local disease surveillance and outbreak control activities, local assessment of immunization levels and coverage, local public awareness activities, and local laboratory services.

These State and local activities are complemented by activities performed at CDC which can either be accomplished better at the national level or which are more cost effective to perform centrally rather than being duplicated in each State and Territory. These activities include: providing technical assistance and consultation in management practices and program operation methods; developing national goals for the prevention and control of childhood vaccine-preventable diseases and the strategies for achieving these goals; reviewing and evaluating State and local immunization programs; maintaining a stockpile of vaccine and jet injector equipment for use to control epidemics or in the event of disruption in vaccine supply; maintaining a mechanism for the saving of millions of dollars annually in the consolidated purchase of vaccines; providing national surveillance of vaccine-preventable diseases and prompt epidemic assistance in the investigation and control of outbreaks of diseases; providing laboratory reference services; rapidly identifying of problems of national significance (e.g., the identification of a "hot lot" of vaccine); developing recommendations for the appropriate use of vaccines; assessing national immunization levels; laboratory proficiency testing and quality control; and conducting studies and investigations to determine the safety, efficacy, and appropriate use of new and current vaccines.

The following 1985 accomplishments reflect the continuing progress being made as a result of multifaceted immunization programs involving a coordinated approach whereby Federal, State, and local governments have worked together toward a common goal:

a. Indigenous measles has been all but eliminated from the United States.

b. Only two case of diphtheria and five cases of polio were reported (provisional data).

c. Only two cases of tetanus and no case of diphtheria were reported in children under age 15 (provisional data).

d. Over twenty-two million doses of childhood vaccine were administered in the public sector.

e. Approximately 16.1 million doses of vaccine were purchased through CDC vaccine contracts for use in State and local immunization programs.

f. All 50 States and the District of Columbia have immunization laws requiring immunization prior to the first entry into school. Forty-six of these areas now have Kindergarten through Grade 12 immunization requirements.

g. Forty-six reporting areas have implemented hospital-based maternal immunization education programs which reach 90 percent of targeted hospitals.

h. Standard immunization record cards have been adopted in all 50 States and the District of Columbia.

The long-range goal of the immunization program is, through immunization, to eliminate indigenous measles, rubella, and congenital rubella syndrome from the U.S. entirely and to reduce poliomyelitis (polio), mumps, diphtheria, pertussis and tetanus to levels so as not to be significant public health problems in the United States. The objectives of the program are to assist in achieving:

- By 1990, reductions in the reported incidence rate of:
    1. Measles to fewer than 500 cases per year, all import-associated.
    2. Mumps, rubella, and pertussis to fewer than 1,000 cases per year.
    3. Diphtheria and tetanus to fewer than 50 cases per year.
    4. Polio cases to fewer than 10 cases per year.
- By 1990, increases in the number of children immunized so that:
    1. Ninety percent of children will be immunized against measles, mumps, rubella, diphtheria, pertussis, and tetanus by the end of their second year of life.
    2. Ninety-five percent of children attending licensed day-care centers and kindergarten-grade 12 should be fully immunized.
- By 1990, refined and improved surveillance and evaluation systems so that:
    1. At least 95 percent of all children through age 18 have up-to-date official immunization records in a uniform format using common guidelines for completion of immunizations.
    2. At least 90 percent of those hospitalized and 50 percent of those not hospitalized with vaccine-preventable diseases are reported.

CENTERS FOR DISEASE CONTROL
CHILDHOOD LEAD POISONING PREVENTION
MENTAL RETARDATION

In young children excessive lead exposure can produce injury to the hematopoietic (blood forming), renal (kidney), and nervous systems. Damage to the nervous systems ranges from severe mental retardation to subtle psychologic deficits, behavioral disorders, and learning disabilities. These latter consequences, which are only now becoming recognized by the general medical community, result from levels of lead exposure previously considered safe and occur in children who are asymptomatic.

Until October 1, 1981, CDC administered the Childhood Lead Poisoning Prevention Grant Program. The goal of the program was to prevent neurologic damage caused by lead; and, to this end, funds were awarded to over 100 communities in 35 States to screen children for lead toxicity and provide medical and environmental followup for those identified with the disease. During the period from 1972 through 1982, local programs screened 4,252,000 children and identified 254,000 with lead toxicity. During each quarter of fiscal years 1979, 1980, and 1981, programs maintained 19,000 - 26,000 children under clinical management for lead toxicity - providing them essential medical and environmental followup services to reduce their risk of lead-induced neurologic damage.

Effective October 1, 1981, the Childhood Lead Poisoning Prevention Grant Program was consolidated into the Maternal and Child Health Block Grant, administered by the Health Resources and Services Administration (HRSA). Under the block grant, States acquire a leadership role for promoting and implementing lead poisoning prevention services at the local level.

In FY 84, CDC convened a federal advisory committee to recommend changes in the CDC lead statement and the new document, Preventing Lead Poisoning in Young Children, was published in early 1985.

CDC continues to work to identify sources of lead in the environment which may be particularly dangerous to children. In cooperation with State health departments and Environmental Protection Agency (EPA), studies (in Kellogg, ID and East Helena, MT) were conducted to measure sources of environmental lead in children and their homes and yards. Both studies are now complete and are undergoing peer review. The Kellogg study has led EPA to plan remedial actions for high soil lead contamination.

HEALTH RESOURCES AND SERVICES ADMINISTRATION
BUREAU OF HEALTH CARE DELIVERY AND ASSISTANCE

MENTAL RETARDATION

Program emphasis on mental retardation was initiated in 1956 as mandated by Congressional earmarkings of funds from the Maternal and Child Health (MCH) program under Title V of the Social Security Act. These funds were used to develop special demonstrations of needed services in each State. Based on the model of a multidisciplinary clinical unit in the community, the demonstrations were designed to provide diagnosis, evaluation of a developmentally delayed or retarded child's capacity for growth, the development of a treatment and management plan, interpretation of findings, counseling of parents, and follow up care. These programs played a significant role in preventing or delaying institutionalization by providing parents with alternatives in terms of management help, treatment, and access to community resources. Over 200 of these "Child Development" programs are still being operated by the States.

As these models were replicated, the activity used portions of basic formula grants, special project grants to institutions of higher learning, and programmatic research grants linking State health agencies, medical centers, and universities to develop a balanced and coordinated program of prevention and service and achieve movement toward the realization of two national goals in mental retardation - prevention and deinstitutionalization.

Biochemical and cytogenetic laboratory units in major medical centers were developed and supported in 1963 by Congressional earmarking of funds from the Crippled Children's program under Title V of the Social Security Act, which provided important tertiary back up services for these special projects. Title V funds were also used to support State and regional newborn screening programs to detect metabolic disorders and provide dietary management and treatment aimed at preventing retardation and damage in the affected infants.

In order to supply the leadership personnel necessary to maintain and extend this emphasis, to demonstrate exemplary service to primary care providers, and to serve as conduits for the transmission of research findings to the service delivery system, University Affiliated Facilities (UAFs) Programs constructed under authority of PL 88-164 received support, from Section 516, Title V, Social Security Act for the health services component. In collaboration with other Federal, State and local support. These programs are serving as comprehensive specialized care and training centers which continue to provide leadership and assistance to the State services delivery system for handicapped and retarded individuals.

Section 508, (PL 88-156) Title V, Social Security Act, authorized grants for projects to help reduce the incidence of mental retardation and other handicapping conditions caused by complications associated with childbearing and to help reduce infant and maternal mortality by providing necessary health care to high-risk mothers and infants. Starting in Fiscal Year 1975, each State was required to incorporate such projects in its State plan and provide the services either directly or through grants and contracts. The long-range impact on prematurity and the presumed decrease in the number of damaged infants produced by these women was studied, and served as models for continuing efforts at prevention.

The use of Title V Block Grants by the States for prevention initiatives related to increased immunizations, the provision of RH immunoglobulin for RH negative women at risk and the continuing effort at lead screening for children has had a noticeable impact on the prevention of mental retardation from these causes.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SOCIAL SECURITY ADMINISTRATION

Mental Retardation

Purpose

The basic purpose of the social insurance programs (Old-Age, Survivors, and Disability) is to provide cash benefits to replace, in part, earnings that are lost to individuals and families when earnings stop or are reduced because the worker retires, dies, or becomes disabled. This program is contributory and self-supporting. Benefits are wage-related and entitlement to benefits is an earned right. In January 1974, the Supplemental Security Income program was added to those SSA administers. It provides payments to the needy aged, blind, and disabled, is noncontributory and is financed entirely out of general Federal revenues.

Historical Development

In 1935, when the original Social Security law was passed, the program was to have provided only retirement benefits to aged workers. In 1939, benefits for dependents and survivors were added and benefits become payable in 1940. Protection against long-term total disability--not only for disabled workers, but also for adult sons or daughters (who became disabled before age 18) of disabled, reitred, or deceased workers--was provided by the 1956 amendments. The 1967 amendments provided benefits for disabled widows and widowers age 50 and over. From 1939 through 1974, Congress granted ten general benefit increases in recognition of the fact that prices and wages had increased. In 1972, a section of P.L. 92-336 provided for an automatic benefit increase when the cost-of-living rises by 3 percent or more. Effective January 1974, payments under the Supplemental Security Income program began to qualified aged, blind, and disabled persons, including the mentally retarded.

Economic Impact

Old-Age, Survivors and Disability Insurance (Title II Programs)

Mental retardation is a major factor in about 70 percent of cases involving dependents or survivors who have been continually disabled since childhood. In fiscal year 1985 an estimated 405,000 mentally retarded adults, disabled in childhood, and retarded workers received $1.3 billion in benefits.

The regulations contain standards as to the level of severity required in disability cases involving mental retardation. These regulations (published in 1985) have the effect of law and are available to the public and medical community.

The number of mentally retarded children under age 18 who receive Social Security insurance payments as dependents of retired, disabled, or deceased workers is unknown, since their benefits are payable regardless of disability. Under Social Security's "Childhood Disability" provisions, lifetime monthly payments can be made to a person age 18 or over who has been disabled by mental retardation--or other impairments--since childhood. In many cases, the monthly benefits enable the retarded childhood disability beneficiary to be cared for at home instead of in an institution. Furthermore, as more and more retarded people outlive their parents, the program offers reassurance to fathers and mothers who know that financial help for their disabled child will be forthcoming even after their deaths. About 56 percent of the childhood disability beneficiaries are age 35 and over and about 33 percent of them are age 45 and over.

If the parents are dead, a relative or other party who has demonstrated a continuing interest in the beneficiary's welfare, a welfare agency, or a legal guardian man be chosen as representative payee to handle the benefit funds and to plan their use on behalf of the beneficiary. Each representative payee is held accountable for the way in which the benefits are used.

Supplemental Security Income (Title XVI)

An estimated 450,000 retarded individuals who are not entitled to benefits under the title II Disability Insurance program were receiving payment under the Supplemental Security Income program by the end of fiscal year 1985.

Activities and Achievements

Since 1970, the Social Security Administration has conducted biennial onsite reviews in State mental hospitals and schools for the retarded. The program focus is an indepth examination of the way in which these institutions are managing Social Security benefits on behalf of patients who receive their checks through an institutional official serving as "representative payee."

The observations and conclusions resulting from a State review are, after analysis, communicated to the State Commissioner for this use in the development of improved practices in the State's system. Findings also serve as a basis for SSA program and policy evaluation. The onsite approach is expected to strengthen relationships with the States, improve their understanding of their responsibility for optimum use of benefits when serving as representative repayee, and open new channels for the discussion of problems and practices affecting the well-being of all beneficiary-patients in State mental institutions.

SSA has participated in the Special Program for Employment of the Handicapped to employ the mentally retarded since its inception in 1964. It also has tried to generate interest in the program by private employers and other Federal agencies. In SSA, mentally retarded persons are successfully performing in such positions as mail and file clerks, messengers, operators of printing, xerox, card reader machines, and key punch machines. As experiment with the color coding of file cabinets and cartridges of microfilm has proven highly successful in broadening employment opportunities for the mentally retarded to an area of work which requires a very high degree of accuracy.

SOCIAL SECURITY ADMINISTRATION

Annual Payments to the Mentally Retarded
FY 1983 - FY 1987
(In Millions of Dollars)

	1983 Actual	1984 Actual	1985 Actual	1986 Estimate	1987 Estimate
Estimated Benefit Payments from OASDI Trust Funds.............	$1,175	$1,250	$1,300	$1,350	$1,400
Estimated General Fund Payments for Supplemental Security Income....................	1,045 1/	1,006 1/	1,183	1,282	1,391
Total, Social Security Administration.....................	$2,220	$2,256	$2,483	$2,632	$2,791

1/ Due to Federal legislation mandating check payment on a banking day, the SSI program made 13 monthly payments in FY 1983 and 11 payments in FY 1984.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

Medicaid Program

Title XIX of the Social Security Act provides for a program of medical assistance for certain low-income individuals and families. The program, known as Medicaid, became Federal law in 1965. Medicaid is financed jointly from State and Federal funds with varying Federal contribution rates to each State. It is administered by State and local governments within broad Federal requirements and guidelines. In FY 1985, 56 States and jurisdictions were participating in Medicaid.

Medicaid is primarily designed to provide medical assistance to those groups or categories of people who are eligible to receive cash payments under one of the existing welfare programs established under the Social Security Act. Generally, payments received under one of these programs means automatic eligibility for Medicaid. With the federalization of the adult categories on January 1, 1974, under the Supplementary Security Income (SSI) program, however, States are not in all cases required to provide Medicaid to all adult recipients of cash assistance under title XVI, as was the case in the past under titles I, X, XIV, or XVI. Limited Medicaid coverage of SSI cash assistance recipients will apply in States which, in determining Medicaid eligibility, opt to apply any eligibility criteria from the January 1, 1972, medical assistance standard which is more restrictive than the eligibility requirements for the Federal title XVI program for aged, blind, and disabled individuals. States which retain any eligibility factor(s) from their January 1, 1972, standard which is (are) more restrictive than the title XVI eligibility factor(s) must deduct a person's medical expenses from his income in determining eligibility. (They are not required to cover title XVI cash assistance recipients who have higher income or resources, or who otherwise do not meet the January 1972 medical assistance standard). As of October 1, 1984, 14 States and jurisdictions have restricted Medicaid eligibility of SSI recipients under this option.

Thirty States and the District of Columbia extend Medicaid coverage to all recipients of cash assistance under the SSI program. States also have the option of providing Medicaid coverage to persons receiving a State Supplemental payment, subject to certain limitations. Six States have elected to establish eligibility criteria within the guidelines of both the title XVI and the January 1, 1972, medical assistance standards. The five territories, because of their Federal matching limitations, are not identified as using either standard. In addition, States may still elect to cover certain medically needy persons who are eligible for help only with their medical bills and who do not receive maintenance payments.

Certain mandatory services must be included in Medicaid State plans. These include: inpatient hospital care; outpatient care; physician services; skilled nursing facility services and home health services for individuals 21 years of age and older; rural health clinic services; early and periodic screening, diagnosis and treatment services for children under 21; lab and X-ray services; and family planning services. In addition, States may cover a range of optional health services including dental care, drugs, eye-glasses, intermediate care facility services, and others.

Mental Retardation

Effective January 1, 1972, P.L. 92-223 transferred intermediate care services to title XIX as an optional service and authorized the provision of intermediate care facility (ICF) services in public institutions for the mentally retarded if the institution provides health or rehabilitative services and if the eligible individuals are receiving active care and treatment. To assure that the Federal dollars made available for such institutional care could lead to higher quality care and services in an improved environment, and not simply to a replacement of State dollars, the legislation contained a provision requiring the States to maintain their own fiscal effort.

Forty-six States and the District of Columbia responded to the title XIX authority by adding to their State plan coverage of ICF services in public institutions for the mentally retarded. Prior to January 1, 1972, some 17 States claimed Federal matching for the mentally retarded in institutions which qualified as skilled nursing homes. It should be noted that because services in the past were being provided to the mentally retarded as skilled nursing home services, the adoption of the intermediate care facility program resulted in a redesignation of facilities in some States. The result is that these facilities are able to provide services at a more appropriate level of care in instances where skilled nursing care is not medically necessary. States, however, continue to provide care for the mentally retarded in skilled nursing facilities where medically appropriate. Also, Section 2176 of the Omnibus Budget Reconciliation Act of 1981 allows States to provide care in the home by community-based services through an approved waiver process. HCFA has approved 48 waivers to provide home and community-based services to the mentally retarded and developmentally disabled since the enactment of Section 2176.

Total Federal expenditures for services for the institutionalized mentally retarded (in ICFs only) are estimated to be $3,105 million in FY 1987. Estimates are not available on the number of Medicaid dollars expended on all other Medicaid services provided to the mentally retarded. It should be emphasized that the Medicaid eligible mentally retarded person may receive the full range of Medicaid services, and receive them on the same basis as the rest of the Medicaid eligible population.

ESTIMATED FEDERAL MEDICAID EXPENDITURES FOR INTERMEDIATE CARE FACILITIES/MENTALLY RETARDED

($ in millions)

FY 1985	FY 1986	FY 1987
$2,682	$2,928	$3,105

MIGRANT PROGRAMS

MIGRANT PROGRAMS

Federal Funds Expended for Migrants
(amounts in thousands of dollars)

	1983 ACTUAL	1984 ACTUAL	1985 ACTUAL	1986 ENACTED	1986 POST-GRH	1986 REV'D BUD	1987 ESTIMATE
Health Resources and Services Administration:							
Bureau of Health Professions -- Area Health Education Centers...	808	112	180	180	172	80	-0-
Bureau of Health Care Delivery and Assistance.....	38,104	42,100	44,300	45,400	44,946	44,300	a/
Subtotal...	38,912	42,212	44,480	45,580	45,118	44,380	-0-
Human Development Services:							
Administration on Children, Youth, and Families -- Head Start Program..	32,637	35,398	38,261	38,260	37,622	37,622	38,879
Total Migrants Programs...	71,549	77,610	82,741	83,840	82,740	82,002	38,879

a/ Included in the Primary Health Care Grants to States.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Bureau of Health Professions

MIGRANT HEALTH

In FY 1985, the Area Health Education Center program provided funds to the University of California-San Francisco, University of Arizona, Eastern Virginia Medical Authority, and Michigan State University for migrant health activities. These awards totaled $180,000 and impacted approximately 24,980 individuals. The largest award of $93,000 was made to Eastern Virginia Medical Authority.

The Texas Tech University for the Health Sciences General Internal Medicine/General Pediatrics Residency Training program indicated activities in migrant health; two physician assistant programs also provide training in this area; and, one Family Medicine Department program reported Migrant Health activities.

(Amounts in dollars)

	1983 ACTUAL	1984 ACTUAL	1985 ACTUAL	1986 ENACTED	1986 POST-GRH	1986 REV'D BUD	1987 ESTIMATE
Area Health Education Centers..	808,000	112,000	180,000	180,000	172,000	80,000	-0-

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Bureau of Health Care Delivery and Assistance

MIGRANT HEALTH

The purpose of the Migrant Health program is to assure access to and the provision of an adequate level of health care services for migrant and seasonal farmworkers and dependents. In Fiscal Year (FY) 1985, grants were made to public and private non-profit organizations.

During this period the Migrant Health program supported 122 migrant health centers including six birthing centers. These centers provided the main source of health services to their families. By September 30, 1985, these centers provided services to approximately 500,000 persons.

These centers and projects provided primary health services, such as physician services, diagnosis and treatment, as well as laboratory, pharmacy, and emergency services. Supplemental services are provided as appropriate, such as home health services and dental outreach, as well as inpatient and outpatient hospital care. In addition, inpatient hospital care was provided to migrants and their families in selected areas of special need through the Migrant Hospitalization Program. Priority was given to high-risk mothers and infants.

In Fiscal Year (FY) 1985 the program received an increase of approximately $2.2 million. This allowed for services to be expanded to provide additional services to 40,000 migrant and seasonal farmworkers and their families through approximately 3 new health centers.

The Fiscal Year (FY) 1986 activities will focus on maintaining the numbers of migrant and seasonal farm workers being served, and the preventive health services being provided through existing MHCs, and coordination with local migrant related agencies. In FY 1986, we estimate that 500,000 migrant and seasonal farm workers will be served by 125 Migrant Health Centers.

(amounts in dollars)

	1983 ACTUAL	1984 ACTUAL	1985 ACTUAL	1986 ENACTED	1986 POST-GRH	1986 REV'D BUD	1987 ESTIMATE
Head Start Migrant Program.	38,104,000	42,100,000	44,300,000	45,400,000	44,946,000	44,300,000	1/

1/ Included in the Primary Health Care Grants to States.

HUMAN DEVELOPMENT SERVICES

Administration for Children, Youth, and Families

MIGRANT DAY CARE PROGRAM

The Indian and Migrant Program Division in the Administration for Children, Youth, and Families funds grantees to provide comprehensive developmental services to migrant pre-school children and their families.

Because of the unique needs of migrant farmworking families, programs had to be designed to provide the family with access to these resources without creating economic or other hardships. Resources alone, without an adequate system of delivery, will not solve the problems of migrant families with pre-school children.

The children are served through a basic program design which incorporates Head Start standards and quality child care services. This design calls for some structural modifications of the traditional Head Start program including: (1) extending the hours of operation to coincide with the parent's working hours; (2) allowing all pre-school children to participate, including infants, and (3) utilizing bilingual and bicultural staff where needed. These modifications are necessary in order to provide the type of full service program which is tailored to the needs of migrant families.

Head Start funds for training and technical assistance projects provide direct assistance to Migrant Head Start programs. Other ACYF funds are used to support child abuse prevention and treatment activities in Head Start programs and experimental and research activities.

(amounts in dollars)

	1983 ACTUAL	1984 ACTUAL	1985 ACTUAL	1986 ENACTED	1986 POST-GRH	1986 REV'D BUD	1987 ESTIMATE
Head Start Migrant Program.	32,637,000	35,398,000	38,261,000	38,260,000	37,622,000	37,622,000	38,879,000

MULTIPLE SCLEROSIS

Obligations

Public Health Service:	1983	1984	1985	1986 Appropriation	1986 Available After Sequestering	1986 Revised Estimate	1987 Estimate
National Institutes of Health:							
National Institute of Neurological and Communicative Disorders and Stroke..............	31,080,000	35,459,000	40,235,000	44,012,000	42,119,000	41,149,000	40,714,000
National Institute of Allergy and Infectious Diseases...............	15,113,000	16,352,000	20,509,000	21,118,000	20,201,000	20,103,000	19,487,000
Total, NIH..........	46,193,000	51,811,000	60,744,000	65,130,000	62,320,000	61,252,000	60,201,000

NATIONAL INSTITUTES OF HEALTH

National Institute of Neurological and Communicative Disorders and Stroke

MULTIPLE SCLEROSIS

Multiple sclerosis (MS), an unpredictable, chronic disease of the central nervous system, is the foremost crippling disease of young adults. It afflicts some 123,000 Americans, with 8,000 new cases diagnosed each year. The largest proportion of these new patients are white females between the ages of 30 and 50. MS has been shown to be twice as prevalent among women as among men, and twice as prevalent among whites as among nonwhites.

Because MS strikes in the prime of life and causes long-term disability, the resulting financial and emotional burden on patients and families can be very high. Income for the afflicted patient is reduced as a result of unemployment, decreased wages, or shortened work hours. Patients also face high medical costs as well as additional expenses incurred for housekeeping assistance or modifications needed to allow continued use of a house or car. A national survey commissioned by the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) has estimated total lifetime losses for the MS population in the United States to be $28 billion.

In the MS patient, the brain and spinal cord can become powerless to control such functions as movement and speech. Nearly all MS patients experience muscle weakness, numbness, difficulty with coordination, and loss of balance sometime during their illness. Many suffer visual disturbances, often as an initial manifestation of the disease. Speech difficulties and dizziness are common. Late in the disease, many patients lose bowel or bladder control.

This variety of symptoms reflects the nervous system's seemingly haphazard dysfunction. In MS, the long axons extending from nerve cells in the brain and spinal cord randomly lose their enveloping sheath of myelin, a protective cloak needed for high-speed transmission of electrical messages in the nervous system. Scar tissue forms wherever myelin is lost. As a result, there is blocking or slowing of messages moving along the nerves back and forth between the brain, the spinal cord, and all parts of the body.

The course of multiple sclerosis generally follows several patterns. For example:

o Relapsing/remitting. In this form of MS, patients experience episodic attacks, called relapses, in which new symptoms appear or old symptoms worsen. These attacks are followed by periods of partial or complete recovery known as remissions.

- Remitting/progressive. Perhaps the most common form of the disease, remitting/progressive MS is similar to the relapsing/remitting form, but the patient's clinical condition deteriorates with each attack.

- Chronic progressive. This is the most devastating form of MS. In this form, patient's symptoms worsen steadily without remission. Usually the decline is slow, but an unfortunate 10 percent of patients experience a swift and relentless downhill course to total disability.

- Benign. About 20 percent of MS patients have a form of MS in which there is an arrest of the disease with little or no progression after an initial episode.

MS Research: A Coordinated Effort

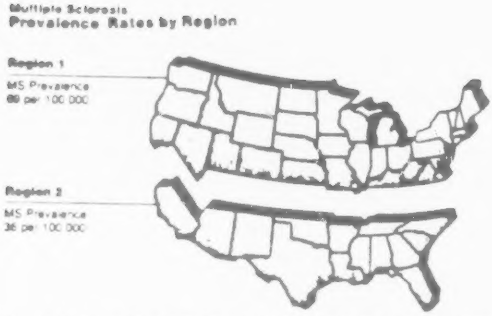
NINCDS is the focal point within the Federal Government for MS research. The NINCDS supports basic and clinical studies on MS in intramural laboratories at the National Institutes of Health and grantee institutions.

Other arms of the Department of Health and Human Services studying aspects of MS include the National Institute of Allergy and Infectious Diseases; National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases; National Institute of General Medical Sciences; National Heart, Lung, and Blood Institute; Division of Research Resources; and Centers for Disease Control.

The Veterans Administration, the National Science Foundation, National Institute for Handicapped Research, and the Department of Defense are also studying various aspects of this many-faceted disease. In the private sector, the National Multiple Sclerosis Society provides significant support in all areas of MS research.

Epidemiology of Multiple Sclerosis

Many investigators have reported that MS is more prevalent in temperate climates, such as those found in the northern United States, Canada and Europe, than in tropical regions. A survey conducted under an NINCDS research contract found that prevalence rates almost doubled above the 37th parallel, which, in the United States, runs from Virginia to California (see illustration).



Until now, little has been known about how long MS patients in different latitudes live after the onset of symptoms. NINCDS grantee Dr. Barbara R. Visscher at the University of California in Los Angeles has found that although the probability of developing MS is less in low-risk areas, the disease may follow a more severe course. Also, MS patients in high-risk areas live longer, on the average, than MS patients in low-risk areas.

Scientists are intrigued by periodic reports of an unusually high number, or cluster, of MS cases in a particular geographic area. Most such occurrences prove to be chance associations. But scientists feel compelled to look into each report, because a true MS cluster would provide unusual research opportunities. This year, NINCDS intramural scientist Dr. Bruce S. Schoenberg began collaborating with the National Multiple Sclerosis Society to develop the first formal mechanism for evaluating MS clusters. Criteria currently being tested seek to answer such questions as:

- Do the patients really have MS? Since other disorders have many of the same symptoms, investigators must rule out possible misdiagnoses.

- How big an area does the cluster cover? The answer to this question defines the population "at risk." All the diagnoses may be reported by one physician or one institution, but the patients may come from a large area.

- Are there any new factors in the affected area that might account for the seemingly sudden rise in the numbers of MS cases? For instance, a new neurologist in an area previously lacking in or underserved by such specialists could be responsible for a rise in the number of reported cases simply because the disease was not previously recognized as MS.

Studies of this nature can help scientists in their efforts to understand, treat, and eventually prevent MS by giving them a better overall picture of the environmental and genetic aspects of the disorder. With sufficient epidemiological data, investigators can test hypotheses related to possible causes of the disease, determine the population at risk, and be more accurate in their prognoses.

Advances in Immune System Studies

Scientists have been studying the possibility that in MS the immune system--the body's major mechanism for resisting disease--overreacts to some triggering factor and mistakenly directs a defensive attack against the body's own tissue. One suspected triggering factor is the measles virus. NINCDS intramural scientist Dr. Henry F. McFarland recently discovered that measles-fighting cells--helper T cells which, along with suppressor T cells, regulate antibody production--must recognize two signals before they will launch a defensive attack against the measles virus. The signals consist of the measles virus and HLA class II antigens. (HLA antigens are cell-surface molecules that the immune system "reads" to distinguish between self and non-self. Most T cells react to HLA class I antigens.)

This discovery enabled Dr. McFarland to measure measles-fighting T cells in the immune systems of MS patients and normal volunteers. He found that most MS patients have fewer measles-fighting cells than normal individuals or those with other diseases. If measles-fighting cells, or the measles virus itself, can be implicated in the cause of MS, scientists may be able to find ways to intervene and prevent MS attacks.

Two NINCDS grantees, Dr. Paula Dore-Duffy at the University of Connecticut Health Center in Farmington and Dr. Jean Merrill at the University of California in Los Angeles, this year reported information that sheds new light on the MS patient's immune system. In a collaborative study, the investigators found that macrophages (cells that facilitate the production of antibodies) from MS patients produce large amounts of a substance called prostaglandin E2, or PGE_2. PGE_2 causes two kinds of changes in immune system cells: suppressor T cells lose markers on their surface, making them impossible to count; and natural killer cells--another type of immune cell that does not need antibody to kill various cells--lose their ability to destroy their targets. If investigators can determine how PGE_2 causes these reactions, they may be able to explain the abnormalities so often seen in an MS patient's immune system.

Dr. Dore-Duffy has also observed that PGE_2 levels appear to increase and peak at, or just prior to, the onset of clinical symptoms. Levels fall dramatically within the first two weeks of an attack, then rise to pre-attack levels or higher during remissions. This suggests that PGE_2 is affected by the disease process, and may be responsible for regulating the function of the T cells of the immune system in MS patients.

In MS, as in many other central nervous system disorders, immune cells cross the blood-brain barrier, a tightly structured membrane that generally limits access of many substances to the brain. NINCDS intramural scientist Dr. Dale E. McFarlin is continuing to study how immune cells migrate into the brain. If scientists knew how these cells cross the barrier, they might be able to develop methods of preventing immune cells from migrating. Or they might be able to develop substances capable of crossing the blood-brain barrier to treat MS.

MS Clinical Trials

Numerous therapies for MS have been studied, but none has yet been proven consistently effective in altering the course of the disease. The unpredictable nature of MS makes therapies hard to evaluate, as it is difficult to prove that the experimental treatment, rather than a naturally occurring remission, is responsible for improvement.

At Albert Einstein College of Medicine, Yeshiva University, New York, Dr. Murray Bornstein is testing Copolymer I, a synthetic substance similar to myelin basic protein, in patients with relapsing/remitting MS. Results from a two-year, double-blind, NINCDS-supported pilot study reveal that patients treated with copolymer I had significantly fewer attacks than patients given a placebo. Treated patients were more stable in their condition; some even experienced clinical improvement. A larger multicenter trial is being considered.

Dr. Lawrence Jacobs, an NINCDS grantee at the Millard Fillmore Hospital in Buffalo, New York, has been treating remitting/relapsing MS patients with one type of interferon known as beta interferon. (Interferon is an antiviral protein that may modulate the body's immune system.) In the preliminary trial, he has reported that patients receiving interferon had markedly fewer attacks than the control group. Control patients who were subsequently transferred into the group receiving interferon also showed a substantial decline in disease activity after two years of treatment. A follow-up study is now under way.

One drug that induces the body to produce interferon is Poly ICLC. NINCDS intramural scientist Dr. Dale E. McFarlin has nearly completed a study on the effect of Poly ICLC in patients with chronic progressive MS. He has found that this drug is safe for MS patients, and does not cause their condition to deteriorate. Although most patients stabilized or improved while receiving treatment, it is not known whether these results are due to benefit from the drug, a placebo effect, the flu-like symptoms produced by the drug, or the natural course of the disease. Further studies will be necessary to determine the efficacy of Poly ICLC in the treatment of MS.

Diagnostic Tools

Although current tests for diagnosing MS are 95 percent reliable, there is no single test that yields an absolute diagnosis. Scientists are searching for more specific criteria to aid in the early and definitive diagnosis of MS.

Dr. Richard Rudick, an NINCDS grantee at the University of Rochester in New York, has identified a specific laboratory "marker" for MS. Using a technique called radioimmunoassay, Dr. Rudick measured the number of free kappa and lambda chains in the cerebrospinal fluid of patients. Pairs of these chains are important components of antibody molecules. Scientists have long known that immunoglobulin G, a class of antibody, is often elevated in the cerebrospinal fluid of MS patients. Dr. Rudick this year was able to detect the free kappa chain portion of the molecules but not the free lambda chains. These results indicate elevated levels of kappa chains in the cerebral spinal fluid of MS patients. No such elevation is seen in patients with other inflammatory or infectious diseases.

NINCDS-supported investigators led by Dr. George Ellison at the University of California in Los Angeles are studying sensory evoked potentials in relatives of MS patients. Sensory evoked potentials are tests that measure the time it takes for an electrical impulse to travel from the nerves of the eye, ear, or skin to the brain. In MS, demyelinated nerves conduct these impulses more slowly than undamaged ones. Yet the research team this year found that some healthy relatives of MS patients had slower response times than people in a control group. This finding indicates that there may be a significant population with nonsymptomatic changes similar to those present MS patients. It also tends to strengthen the theory that there is a genetic or family influence involved in the development of MS.

National Institute of Allergy and Infectious Diseases

Through their basic research on viral diseases and on immune system disorders, scientists supported by the National Institute of Allergy and Infectious Diseases (NIAID) are making valuable contributions to research on multiple sclerosis (MS).

A major collaborative research effort on MS is under way at the University of California, Los Angeles (UCLA) by scientists supported by both this Institute and the NINCDS. NIAID's long-time grantee, Dr. John L. Fahey, chief of one of the Institute's Centers for Interdisciplinary Research on Immunologic Diseases, is studying the special relationship of the immune system to MS.

MS patients have an imbalance in ratio of two types of white blood cells—T helpers and suppressors—that help regulate the immune system. Certain drugs that affect the immune system have been used to treat MS patients, and these drugs have been beneficial in some cases. However, scientists do not yet fully understand how the drugs act.

In a carefully controlled clinical trial, Dr. Fahey and his colleagues are studying four drugs that suppress the immune system—cyclosporin, prednisone, azathioprine, and cyclophosphamide. They are assessing the immune function of MS patients before, during, and after the use of these drugs. The investigators have found that treatment with one of these immunosuppressive drugs narrows the ratio of helper and suppressor cells, which may be a key to improvement in neurologic function.

They have recently reported that treatment with cyclophosphamide improved the course of chronic progressive MS. Previous studies suggested that the beneficial effect of this drug in MS patients was due to its ability to suppress helper T cells. In this study, clinical improvement was related to increases in suppressor T cells and decreases in helper T cells. These findings coupled with those from other studies strongly suggest a pathogenic role for T cells in the production of clinical signs of MS.

Dr. Fahey and his colleagues are optimistic that the critical information being obtained from these studies will provide physicians with an understanding of the immunologic basis for the successful use of immunosuppressive drugs in treating MS patients.

Another NIAID grantee, Dr. Stephen A. Udem at the Albert Einstein College of Medicine, is studying measles virus and how it reproduces. The measles virus remains a candidate, as do other viruses, for being a possible cause of MS.

Much of Dr. Udem's recent work has focused on the study of subacute sclerosing panencephalitis (SSPE), a serious degenerative disease of the brain that can develop years after a measles infection. This rare disease is an important model that may yield information relevant to MS and other chronic infections.

Dr. Udem is studying measles virus replication during the acute, productive infection. This information is a prerequisite to identifying the mechanism by which persistent measles infections are established and maintained, and to assessing the role played by such infection in the cause of chronic human disease.

Research Outlook

The key to MS remains elusive. But as new technologies are developed and refined, research is yielding a growing body of evidence about the nature of this baffling disorder. Radioimmunoassay, monoclonal antibodies, evoked potentials, and magnetic resonance imaging are just a few of the tools of modern medicine that open new paths for research.

The NIH will continue to sponsor and stimulate studies of multiple sclerosis and to attract and train young scientists for productive work in this field of investigation.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

MULTIPLE SCLEROSIS

According to the 1984 National Hospital Discharge Survey (NHDS), in 1984 an estimated 32,000 patients were hospitalized in short-stay hospitals in the United States with a first-listed diagnosis of multiple sclerosis. The average length of stay for these patients was 11.4 days. About 75 percent of these discharges were females and over half (59 percent) of the patients with a first-listed diagnosis of multiple sclerosis were between the ages of 15-44 years. In addition to those patients with a first-listed diagnosis of multiple sclerosis, an estimated 28,000 patients were discharged with a secondary diagnosis of multiple sclerosis. These are patients who had another diagnosis listed as first or principal but had multiple sclerosis also shown on their medical records.

RURAL HEALTH

Obligations

	1983 Actual	1984 Actual	1985 Actual	1986 Appropration	1986 After Seqestering	1986 Revised Estimate	1987 Estimate
Health Resources and Services Administration:							
Bureau of Health Care Delivery and Assistance...	184,600	198,000	201,302	235,400	232,400	216,650	1/
Bureau of Health Professions..............	2,152,341	3,002,893	3,049,349	3,788,307	3,621,610	678,301	—
Total, HRSA..........	2,336,941	3,200,893	3,250,651	4,023,707	3,854,010	894,951	—
Alcohol, Drug Abuse, and Mental Health Administration:							
National Institute of Mental Health............	1,860,000	1,325,000	1,625,000	1,716,000	1,642,000	— 2/	— 2/
TOTAL, PHS..........	4,196,941	4,525,893	4,875,651	5,739,707	5,496,010	894,951	—

1/ Proposed for consolidation into Primary Care Block Grant.

2/ CSP Program is proposed for rescission in 1986 with no abolishment in 1987.

HEALTH RESOURCES AND SERVICES ADMINISTRATION
Bureau of Health Care Delivery and Assistance

RURAL HEALTH

The Rural Health Program within the Bureau of Health Care Delivery and Assistance (BHCDA) has as its objective the improvement of health care access and service delivery for those persons residing in rural areas of the United States. Initiated in Fiscal Year (FY) 1975, the Rural Health Program developed and integrated health care resources in communities having the greatest medical underservice. By integrating such programs as the Community Health Centers, the Migrant Health Program, the National Health Service Corps and the Appalachian Regional Commission Health Demonstration Clinics Program, a system was developed that addressed the obstacles encountered in serving these population groups in many underserved areas. A more effective distribution of financial medical and personnel resources was established through linkages with secondary and tertiary levels of care and a system of referral and consultation activities with other programs such as the Community Mental Health Centers, Family Planning, Maternal and Child Health, alcoholism programs, etc. A total of 47 projects were developed the first year.

By FY 1980, over 500 rural projects provided access to care for about 2.8 million rural persons. During 1981 and 1982, a number of these centers were phased out of Federal funding because they did not meet the standards of performance and/or did not service high priority medically underserved areas. Many of these still successfully operate with private funding and/or local government support. During this same period, many others were continued and expanded because they had met these standards successfully in areas of considerable need. At the end of FY 84, 390 rural projects were serving approximately 2.5 million rural persons. During FY 84, the Bureau emphasized building rural networks of care. This emphasis will continue in FY 85. It is expected that approximately 2.8 residents of rural America will be served during FY 1985.

Black Lung Clinics

In 1984, black lung services were provided to coal miners in 38 Black Lung Clinics, the vast majority of whom offer services to residents of rural areas. These clinics are funded within other ongoing rural health centers but can also be independent sites providing comprehensive health services in addition to black lung services. The Black Lung Clinics activities began in 1979 and are funded under the Federal Mine Safety and Health Act of 1977.

In 1985, the Black Lung Clinic sites will have sufficient capacity to serve an estimated 47,500 persons.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Bureau of Health Professions

RURAL HEALTH

The Division of Nursing supports projects implementing outreach programs making basic advanced and continuing nurse education programs accessible to individuals and providing rural clinical practicums for nursing students. In FY 1985 the Nurse Practitioner program awarded $440,775 to at least five projects which focus primarily on providing services to population groups residing in rural areas. Evaluation studies of nurse practitioner program graduates have shown that nurse practitioners increase the availability and accessibility of primary health care in rural and other underserved areas.

The Area Health Education Center (AHEC) program is involved in substantial rural activities. This may be as a total or partial component of an AHEC projet in a rural setting. For example, in FY 1985 five projects involving $1,085,000 are considered rural. An additional seven statewide and combined rural/urban projects are involved in rural activities but precise dollar figures are not available. Two examples are: the University of California-San Francisco AHEC which received $433,590 for their activities; and, the University of Medicine and Dentistry of New Jersey that indicated rural activities would impact 44 individuals, but did not request any funds. A total of eleven AHEC projects with rural emphasis have been funded a total of $1,691,842.

Under the Family Medicine Residencies and Training Program, the University of Florida predoctoral training program expressed having activities in the rural health area. Eleven graduate programs indicated providing activities. The University of Utah ($59,027), University of Colorado health Science Center ($126,652) and Sacred Heart Medical Center ($10,786) graduate training programs were the only three receiving funds in FY 1985.

Twelve Physician Assistant Training programs indicted that their students received training in rural areas.

The University of New Mexico and Mercy Hospital and Medical Center were the only two General Internal Medicine/General Pediatrics programs that indicated having activity.

Under the Family Medicine Departments program, three grantees include a rural component.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute of Mental Health

Rural Mental Health

The National Institute of Mental Health (NIMH) addresses mental health needs of populations in rural areas through activities under its Community Support Program (CSP). The Community Support Program is a national effort to promote the development of support systems for the long-term mentally ill, and to improve the quality and appropriateness of services and opportunities for this population. The focus is on individuals who are inappropriately institutionalized in hospitals and nursing homes, and the larger number of such individuals who are living outside of hospitals without adequate housing or life support services. The NIMH has funded several successful CSP projects which serve rural populations.

Community Support Programs in rural States continue to place a significant priority on rural issues. Following the successful Rural Mental Health Conference for the Western States in Logan, Utah, Arkansas will host a similar meeting in the Spring of 1986. Sixteen Southern and Midwestern States are expected to be represented among the 250 attendees.

During FY 1986, rural concerns will be the predominate topic area in the Regional Conferences in Coeur d'Alene, Idaho, and Topeka, Kansas. Housing and job finding in rural areas will receive the most attention in the agendas. Similar interest in rural matters was shown by Alaska, Washington, Nevada, Iowa, and Nebraska in their respective State CSP meetings.

Psychosocial rehabilitation clubhouses are increasingly becoming the focus of the lesser populated States. At a recent meeting in Bellevue, Washington, (Blue Lake Clubhouse), which included CSP State Project Directors from 11 States, there was general agreement that free-standing psychosocial or rehabilitation clubhouses would be preferred over day treatment programs in rural communities. There are several reasons. Costs are lower, the mentally disabled can engage in several different activities, fewer staff are needed, there is greater involvement in the program of the persons who attend, and clubhouses act as "bridges" for the mentally ill after they leave the hospital.

As a result of rural issues arising in several different grant programs in NIMH, consideration is being given to assigning a staff person who would coordinate the various efforts. The Institue is looking into the possibility of having funds set aside for demonstrations programs which could be replicated in other areas.

NIMH has a staff person on an interdepartmental committee which is looking into a range of transportation problems affecting people in small towns and isolated areas.

The NIMH Division of Biometry and Applied Sciences has completed a study under contract to examine the development of Community Support Programs in a set of urban and rural States, and to examine the development of community support systems in a sample of local sites in each of these types of States. Ten urban and ten rural States participated in the study, with additional data for up to six local areas in each of the twenty States. The State level questionnaire examined staffing, resource, and programmatic mobilization to serve the chronically mentally ill, as well as an overview needs assessment of this service population. The local level questionnaire examined the development of essential service components, their integration, and the characteristics of the local chronically mentally ill population. Results from this study are available in a final report from the Institute. The instruments developed through this project have utility for State self-assessments of programs at the State level and services at the local level for chronically mentally ill adults.

The NIMH Division of Biometry and Applied Sciences has also initiated a study of the relationship between service costs and client outcome among chronically mentally ill adults. Based upon data collected in the study described above, one urban State and one rural State will be selected for this research. In each State, three service sites will participate in the study. The study is designed to advance the understanding of cost-outcome methodology when applied to the use of services by chronically mentally ill adults. Results will be available near the end of 1986.

Sexually Transmitted Diseases

Obligations

Public Health Service	1983 Actual	1984 Actual	1985 Actual	1986 Appropriation	1986 Available after Sequestering	1986 Revised	1987 Estimated
Centers for Disease Control:	$47,687,000	$54,695,000	$52,790,000	$56,285,000	$51,865,000	$51,865,000	$55,453,000
National Institutes of Health:							
National Institute of Allergy & Infectious Diseases	16,855,000	18,341,000	24,143,000	24,801,000	23,725,000	23,617,000	22,744,000
National Cancer Institute	5,265,000	5,996,000	8,231,000	9,300,000	9,000,000	7,600,000	7,400,000
National Institute of Neurological and Communicative Disorders & Stroke ...	33,000	34,000	61,000	67,000	64,000	63,000	62,000
National Institute of Child Health and Human Development.....	2 729,000	4,702,000	5,503,000	5,700,000	5,500,000	5,500,000	5,400,000
Division of Research Resources.............	514,000	296,000	469,000	470,000	450,000	450,000	426,000
Total NIH....	$25,396,000	$29,369,000	$38,407,000	$40,338,000	$38,739,000	$37,230,000	$36,132,000
Total PHS....	$73,083,000	$84,064,000	$91,197,000	$96,623,000	$92,604,000	$91,095,000	$91,585,000

Centers for Disease Control
Sexually Transmitted Disease

I. INTRODUCTION

Sexually transmitted diseases (STD) constitute a major public health problem which causes enormous human suffering, costs hundreds of millions of dollars annually, and imposes tremendous demands on medical care facilities. The magnitude of the chlamydia and gonorrhea epidemics, the increasing problem of resistance to antimicrobials (PPNG, CMRNG and most recently tetracycline-resistant *Neisseria gonorrhoeae* - TRNG), the continuing syphilis problem, the specter of the incurable viral STDs - especially genital herpes, human papillomavirus, and the serious complications of these diseases, such as pelvic inflammatory disease (PID), ectopic pregnancies, infertility, genital cancers, and morbidity and mortality in pregnant women and infants, are of major concern to prevention and control personnel. On top of this, the acquired immunodeficiency syndrome (AIDS) has emerged as a preoccupying public health tragedy. It has been conservatively estimated that the total cost of STD exceeds 3 billion dollars annually. The cost of gonorrhea alone exceeds 1.1 billion dollars, a per capita cost of $5.00 each year.

Achieving the 1990's objectives to reduce morbidity and mortality from STD by preventing cases and complications requires a partnership effort and a sharing of responsibility by Federal, State, and local governments, private medicine, and voluntary organizations. The Federal Government supports this partnership and meets its share of this responsibility through direct financial assistance to State, local and territorial health authorities, through basic and applied research efforts, and through national leadership activities. Direct Federal financial assistance supports disease monitoring, screening, sex partner referral services, and other outreach efforts in all States. Basic and applied research efforts are directed toward further characterizing the pathophysiology, host response, epidemiology, and behavioral aspects of these diseases to permit the development of improved diagnostic, prevention, and control methodologies. National leadership activities include technical assistance in planning, developing, and implementing control approaches; technical consultation in reviewing and monitoring control efforts; developing clinical standards and management systems; training; and providing epidemic assistance, disease information, and prevention strategies.

The major Federal foci for assistance to States are the Centers for Disease Control (CDC) and the HHS Regional Offices; and for research, the major foci are the CDC and the National Institutes of Health (NIH), including the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), and the National Institute for Child Health and Human Development (NICHD).

II. BACKGROUND

During the late 1970's and early 1980's, clinicians, public health workers, and policymakers have become increasingly aware of the broader spectrum of infection spread from person to person during sexual contact. Just as importantly, public health officials began to understand the magnitude, both in terms of financial cost and human suffering, of the long term consequences of sexually transmitted infections - primarily infertility, ectopic pregnancy, other types of reproductive loss, and neoplasia. Thus, as a testimony to the comprehensive nature of this discipline, the term "sexually transmitted diseases" (STDs) has gradually replaced the term "venereal diseases".

Today, the more expanded list of STD encompasses *Chlamydia trachomatis* infections, acquired immunodeficiency syndrome (AIDS), genital herpes, human papillomavirus infections, genital mycoplasmas, cytomegalovirus (CMV), hepatitis, vaginitis, enteric infections, and ectoparasitic diseases. Most of these infections are well known to the medical community, but have achieved recent prominence as STD for several reasons. First, new diagnostic approaches have facilitated their study. Second, the true incidence of the STD appears to have increased at an alarming rate. Third, a higher proportion of systemic diseases are being sexually transmitted. Fourth, the key impact of STD on maternal and child health is now apparent.

Nationally, it is estimated that there are nearly 1.8 million cases of gonorrhea annually, about 90,000 new cases of syphilis, 1.2 million cases of nongonococcal-nonchlamydial urethritis, 3 million chlamydial infections, 200,000 to 500,000 cases of genital herpes, 200,000 cases of Hepatitis B, 3 million cases of trichomoniasis, 1 million cases of external genital human papillomavirus infections, and 1 million cases of other sexually transmitted diseases. More than 1 million cases of PID are diagnosed and treated each year resulting in approximately 276,000 hospitalizations (42 percent of these are younger than age 25 and 82 percent are younger than age 35), 110,400 major surgical procedures (including almost 40,000 hysterectomies), and almost 70,000 ectopic pregnancies each year.

Women bear an inordinate share of the physical and emotional burden of miscarriages, deaths, mental retardation, and other afflictions of children affected by STD. Approximately 155,000 of the babies born each year will have chlamydial infection. For pregnant women with untreated syphilis, the risk of death of the infant is 40 percent, of delivery of a congenital syphilitic infant is 40 percent, and of the delivery of a normal infant only 20 percent. About 3 of every 10,000 newborns are infected with herpes; more than 50 percent of those not treated will die and half of the survivors will suffer serious and permanent mental damage. Congenital infection by cytomegalovirus (CMV) is estimated to occur in 1.5 percent of all pregnancies, and group B *Streptococcus* is estimated to cause symptomatic disease in 12,000 infants under 3 months of age annually and to cause nearly 5,000 infant deaths.

III. EFFECTIVENESS

Since the initiation of Federal assistance and efforts to control STD, reported cases of syphilis have declined from an all-time high of 575,600 in 1943 to 67,000 in FY 1985. During this same period, first admissions to mental hospitals for syphilitic psychoses have declined by 98 percent and infant deaths caused by syphilis have declined 99 percent. The reported incidence of primary and secondary syphilis decreased by over 9 percent in FY 1985.

Federally-assisted State and local gonorrhea control programs were implemented in FY 1972. Since then the annual increases in reported cases began to slow from 11 percent in FY 1973 to 3 percent in 1976 to stable levels from 1977-80 and finally to reductions in 1981-1984 despite social changes which placed increasing numbers of people at risk for STD. In FY 1985 reported gonorrhea morbidity increased for the first time since FY 1980. The increase probably can be attributed to reporting artifact, increases in the proportion of gonorrhea which is resistant to recommended therapy and to demands of HTLV-III antibody testing and counseling.

IV. PREVENTION AND CONTROL EFFORTS

The CDC provides active leadership and support for national efforts directed toward the control of STD to include: a national system to identify, investigate, and monitor special disease control problems; the timely transfer of technological advances to improve State and local prevention and control programs; and applied research to develop new information about diagnosis, treatment, prevention, and control of all STD.

Project grants awarded to State and local health departments and appropriate public and nonprofit entities emphasize the reduction of morbidity and mortality from these diseases through the development of prevention and control strategies, and the implementation of nationally coordinated control programs focused on disease intervention activities. The basic control program components are: (1) screening high-risk populations; (2) surveillance and control activities directed toward antibiotic resistance; (3) surveillance systems to monitor syphilis among specific populations; (4) sex partner-referral services for patients with gonorrhea, infectious syphilis, or chlamydia; (5) hospital-based surveillance efforts for PID; (6) health promotion efforts directed toward people at risk to prevent exposure and influence the infected to seek prompt medical care for themselves and their sex partners; (7) developing strategies for controlling STD and providing training for clinical skills improvement; and (8) involving the private medical community in all aspects of STD control.

The problems which were first noted in 1976 with gonococcal antibiotic resistance continue. Between FY 1979 and FY 1984, a 14-fold increase occurred; in FY 1985 the number of reported cases increased 70 percent. Los Angeles, New York City, and Miami were particularly affected, reporting almost 64 percent of total cases.

In addition, further biological changes of the gonococcal organism created other outbreaks of resistant strains. For example, non-PPNG, but chromosomally-resistant gonorrhea (CMRNG) initially appeared in early 1983. In FY 1985, 517 cases of CMRNG were reported from 27 States. Additionally, high levels of tetracycline resistant organisms (TRNG) were first identified in FY 1985. Research efforts are being directed toward defining the epidemiology and mechanism of these strains.

STD control programs are placing greater emphasis on the prevention of gonorrhea and its complications. In addition to upgrading the counselling of all gonorrhea patients, programs focus on expanding the screening, counselling, and sex partner referral services to define high risk populations.

Hospital-based programs to manage and prevent gonococcal pelvic inflammatory disease (GPID) are currently reporting over 1800 cases monthly. Cases of GPID currently constitute 8 percent of all reported cases of gonorrhea among women. Sex partner referral services were provided to over 86 percent of all reported GPID cases; over half received therapeutic or prophylactic treatment for gonorrhea and 42 percent of those infected were asymptomatic.

Syphilis control efforts are focused on disease-intervention activities including surveillance, case detection, and prevention, specifically of congenital syphilis. Followup of reactive serologic tests for syphilis resulted in the reporting of over 25,000 previously unknown/untreated cases of syphilis. During FY 1985, counselling/sex partner referral efforts were provided to individuals with infectious syphilis resulting in 9,000 new cases of syphilis being identified and treated and 26,700 exposed sex partners receiving preventive treatment. These screening and outreach efforts prevented an estimated 5,500 new cases of syphilis in fiscal year 1985.

V. HEALTH PROMOTION

All sexually transmitted disease control project grants to State and local health departments include information and education activities as an integral portion of their control strategies. Control programs emphasize patient education/counselling designed to improve patient compliance during treatment, reduce the potential for future infection, and encourage the timely referral of sexual partners. In FY 1985, CDC continued a special 318(b) grant to the Educational Development Center (Newton, Massachusetts) to evaluate possible STD health education/risk reduction strategies. Special 318(b) grants were also continued to Indiana University and to Georgia State University to pilot test and develop computer-based instruction modules for a prototype STD reference teacher's manual and student's textbook for grades 6-12.

Through a grant with the American Social Health Association, the CDC provides support to the National STD Hotline, which in FY 1985 used volunteers to provide STD information and referral services to over 64,000 callers. The majority of calls are from teenagers and young adults; in FY 1985 almost 17,000 callers were referred to STD medical services.

VI. CLINICAL SERVICES/TRAINING

Adequate clinical management of patients and their partners is the final common pathway of STD control. However, in the United States clinical services vary widely in different settings and are often inadequate to provide appropriate care for STD patients. Whether patient care is provided by experts at special STD clinics with sophisticated laboratory support, or by primary clinicians with limited laboratory facilities, the objectives of clinical management are the same: (1) To determine the most likely etiology of the patient's complaint; (2) to provide appropriate treatment for that condition; (3) to detect other STD; (4) to ensure patient followup for test of cure after treatment; (5) to manage properly those patients who failed treatment; (6) to identify sexual partners for appropriate evaluation and treatment; and (7) to educate patients to reduce their risks of further disease acquisition. Thus, all key STD control strategies are contained in the microcosm of clinical services.

Because medical school curricula in the United States have not kept pace with the increasing incidence of STD over the past decade, an integral part of STD control strategies has been to develop a coordinated system for training health care providers in the rapidly changing field of STD. This training involves all specialties affecting STD control and has several approaches. STD Clinic Quality Assurance Guidelines (QAG) were updated to assist STD facilities improve patient management. STD treatment recommendations were also updated to reflect changing diagnostic capabilities, antibiotic susceptibilities, and pharmacological breakthroughs. Policy Guidelines for Prevention and Control of Chlamydia trachomatis Infections were developed in response to the emerging need for chlamydia control programs in this Nation. These documents are rapidly distributed to the field and provide public health professionals with access to standardized guidelines which can be adapted to their local needs.

STD Prevention/Treatment Centers have been established at 8 full-time and 2 part-time sites. Each center is based on integration of a university medical school with a model public STD clinic for purposes of providing training for health care providers, and medical, and nursing students. By FY 1985, almost 10,300 students had been cumulatively trained since 1979.

Another priority is the development and evaluation of pilot STD curricula in medical schools. While the STD Prevention/Training Centers have been a very important first step in training mid-level practitioners, there is still a need to reach clinicians during their initial formal training. In this way, a cadre of STD specialists - medically qualified clinicians who have an initial knowledge of, and hopefully a career commitment to, the STD field can be created. In FY 1985, six special 318(b) grants were continued to university medical schools to develop the pilot curricula.

VII. RESEARCH

Both basic and applied research are crucial to STD control. Major changes in intervention strategy have accompanied the introduction of new antibiotics (e.g., penicillin), the development of better detection methods (e.g., Thayer-Martin media), the identification of resistant organisms (e.g., PPNG, CMRNG, TRNG), and the recognition of high-risk groups (e.g., homosexuals, patients with repeat infections, women with PID). Presently, quantum leaps in STD control programs await such developments as effective vaccines against herpes, gonorrhea, and AIDS.

Most STD research in the United States is supported by NIH and CDC, although an increasing amount is funded either by voluntary organizations concerned with the magnitude of the STD problem or by pharmaceutical firms or medical diagnostic companies aware of the potential market. The objectives of this research are to characterize the pathophysiology, host response, and epidemiology of STDs to allow further development of improved diagnosis, treatment, prevention, and control strategies.

NIH supports a variety of basic science and clinical projects. These include development of gonococcal and herpes vaccines, experimental clinical trials with antiviral agents, establishment of herpes transmission patterns within communities, and determination of host responses to chlamydia infections. NIH also sponsors training of post-doctoral fellows in clinical and microbiologic STD research and has undertaken periodic workshops to update the most rapidly advancing areas of STD knowledge.

CDC conducts applied research directed toward monitoring practical results and evaluating control strategies. This involves clinical research, epidemiologic studies; programmatic investigations, and related social science studies.

VIII. PROGRAM ACCOMPLISHMENTS, FY 1985

A. Gonorrhea

- 7.4 million women were cultured; 301,500 (4.1%) were positive; 95% were located and treated.
- 190,600 sex partners were examined.
- 171,000 new gonorrhea infections were prevented.
- Benefit to cost ratio of screening and outreach activities estimated to be over 3:1.
- Identification of tetracycline-resistant *Neisseria gonorrhoeae*.
- Conducted six outbreak investigations of resistant organisms.
- Completed study on variables affecting cost effectiveness of interviewing/investigation.
- Continued studies on organism/host, diagnosis/treatment, surveillance, epidemiology, and prevention/control.

B. Chlamydial Infection

- o Doubled the expenditure for chlamydia activities (estimated $4.5 million).
- o Continued cooperative agreement with University of California San Francisco Institute for Health Policy Studies to develop, study and evaluate cost-effective analytical models for defining chlamydia control strategies.
- o National policy guidelines for prevention and control of chlamydia developed and promulgated.
- o Chlamydia control demonstration projects funded under Section 318(b) in five project areas to test various control strategies.
- o Comprehensive chlamydia control programs now exist in 17 States; 37 test, 48 treat and 45 counsel chlamydia patients in STD clinics.
- o Completed pregnancy outcome studies in Atlanta, Gallup, and Tucson.
- o Descriptive epidemiologic studies of prevalence of chlamydia and risk factors for infection were completed in Denver, Atlanta, and Columbus.

C. Syphilis

- o 32 States and the District of Columbia reported lower primary/secondary syphilis rates in FY 1985 than in FY 1984.
- o 25,200 (26.8 percent) of 94,000 persons with reactive tests were identified and treated as a result of health department followup.
- o Sex partner referral activities resulted in 88,000 suspects referred, 9,000 new cases detected, and 26,700 patients preventively treated.
- o Outreach efforts in syphilis control resulted in the prevention of 5,500 new infections.
- o Continued research on cellular immunology and serodiagnostic methods for congenital syphilis.

D. Human Papillomavirus (HPV) Infection

- o Continued research on the epidemiology of external genital wart infections.
- o Continued research on the comparison of diagnostic techniques for HPV infection.
- o Continued research on an antigen-antibody detection system.

E. Herpes Simplex Virus Infection (HSV)

- o Continued cooperative studies to further define the epidemiology and natural history of HSV.
- o Completed contract for pilot study to develop a national hospital-based surveillance system for neonatal HSV infections; in 18 months, 195 cases were reported.
- o Completed collection of data on host psychological factors related to HSV infections.
- o Continued study on HSV and pregnancy outcome.
- o Began collaborative effort with FDA and pharmaceutical industry to monitor long-term toxicity and viral resistance to acyclovir.

F. Other STD

- o Conducted outbreak investigations of apparent metronidazole resistant cases in Philadelphia and of chancroid in New York City, Orange County, Florida, and Boston.
- o Continued alternate treatment studies for trichomonal infections.
- o Continued collaborative project to develop a serologic test for chancroid utilizing enzyme immunoassay (EIA).

IX. PLANS FOR FY 1987

STD priorities are continually evolving because new STD are emerging as serious public health problems requiring innovative approaches to diagnostic, prevention, therapeutic, and case management services. Although the control of gonorrhea and syphilis will continue to be a major foci for control efforts in FY 1987, chlamydia control strategies will also receive emphasis within the limits of available funding.

Interviewing/counselling of all persons with STD will be upgraded, especially to young patients with their first STD infection, to patients with repeat infections, and to women with pelvic inflammatory disease (PID). Educational efforts will continue to focus on high-risk populations, particularly STD patients, providers of medical care services, and the general public. Technical assistance and consultation to State and local health departments will emphasize improving diagnostic, clinical, and management techniques. Prevention/education efforts will also seek to build a network with community organizations representing groups at risk to use resources in the most efficient manner possible.

Support will continue in major metropolitan areas for hospital-based programs to prevent and control pelvic inflammatory disease including infections caused by both gonorrhea and chlamydia. Research efforts will emphasize defining additional risk factors, diagnostic techniques, prevention strategies, and therapeutic modalities.

Efforts to standardize, expand and upgrade the quality of data collection, analysis, interpretation, and use at the Federal, State, and local level will be continued. In addition to the seven management information systems already established, a microcomputer-based data network will be implemented in all State and selected local health departments which will provide a standardized approach to STD control program decision making.

Training efforts in FY 1987 will focus on the further development of clinical experience in STD for students during their medical school and residency years. Existing STD prevention/training programs will be adjusted as new information or needs are identified and to ensure maintenance of the highest public health and clinical care standards. STD management in FY 1987 will emphasize additional skills in epidemiology to set priorities and provide the maximum yield per STD dollar invested.

Surveillance and operational research related to the sexually transmitted diseases will continue to seek to meet those objectives in place for the current fiscal year. Disease-specific attention will be paid to gonococcal and chlamydial infections, syphilis, genital herpes and trichomoniasis, human papillomavirus (HPV), as well as other STD's. Research to highlight the prevention of STD syndromes of greatest public health concern - infertility, ectopic pregnancy, pelvic inflammatory disease, and adverse reproductive outcomes - will be continued. Increased efforts will be directed toward the emerging problem of antibiotic resistance. Well-controlled clinical trials of promising therapeutic alternatives for infections caused by resistant organisms will be undertaken. Studies to better define the problem of *Chlamydia trachomatis* and to seek public health applications of existing and new technologies will be continued. Studies will be continued to evaluate the toxicity and viral resistance of oral acyclovir for recurrent genital herpes.

Prevention of infertility (inability to conceive, fetal wastage, stillbirth, and neonatal death) depends on the ability to understand the relationship of sexually transmitted organisms to this outcome. The CDC will continue in the following areas of research to identify and reduce the incidence of unplanned infertility attributed to STDs: documenting the impact of STDs on the age- and race-specific infertility trends in the United States during the 1970's and the 1980's; determining the magnitude of the infertility risk in American women suffering episode(s) of pelvic infection; establishing the etiologic role of particular sexually transmitted organisms in causing unplanned infertility; designing experimental studies of prophylactic therapies for women with first episodes of pelvic infection to reduce their risk of repeat episodes, and thus prevent future unplanned infertility; and studying the relationship of STD to fertility-related behavior.

NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases

SEXUALLY TRANSMITTED DISEASES

Sexually transmitted diseases remain serious problems in the United States and throughout the world. Although the numbers of cases of syphilis and gonorrhea have declined slightly in the past five years in the United States, they continue to increase in two-thirds of the world. Chlamydial infections, genital herpes, and genital warts are widespread, particularly among young adults.

The consequences of sexually transmitted diseases include infertility, complications of pregnancy, infant morbidity and, possibly, cancer. In this country, 33 to 50 percent of infertile women have scarred or blocked fallopian tubes due to pelvic inflammatory disease (PID) caused primarily by chlamydial or gonococcal infection; in developing countries, closer to 75 percent of infertile women have tubal damage. Damaged fallopian tubes can prevent the normal passage of a fertilized egg to the womb; resulting in ectopic pregnancy. The number of ectopic pregnancies, each of which represents at least one fetal death, increased in the United States from about 17,000 in 1970 to more than 50,000 in 1980.

In 1981, a lethal new sexually transmitted disease appeared, acquired immunodeficiency syndrome (AIDS), for which, at the present time, there is no effective treatment. The efforts of the National Institute of Allergy and Infectious Diseases (NIAID) to understand and combat AIDS are discussed in a separate report.

The challenge presented by the other sexually transmitted diseases is being met by NIAID intramural scientists and by established investigators throughout the country supported by grants and contracts.

In addition to support of individual investigators, the NIAID has established multidisciplinary Sexually Transmitted Diseases Research Units at several universities. In 1985, one was established at the University of Texas Health Science Center in San Antonio under the direction of Dr. Joel Baseman. Similar units are located at the University of Washington in Seattle (Dr. King Holmes), the University of North Carolina in Chapel Hill (Dr. Frederick Sparling), The Johns Hopkins University in Baltimore (Dr. Keerti Shah), Emory University in Atlanta (Dr. Andre Nahmias), Indiana University in Indianapolis (Dr. Robert Jones), and the University of California at San Francisco (Dr. George Brooks).

Gonorrhea

About one million cases of gonorrhea are reported each year in the United States, but experts estimate that the true incidence may be twice that number. The number of cases in this country may be declining somewhat. However, this decline is offset by a high incidence in developing countries due, in part, to worldwide increases in gonococcal resistance to current antibiotic treatment.

Most cases of penicillin-resistant gonorrhea are due to a strain that produces penicillinase, an enzyme that destroys penicillin and related antibiotics. Dr. Holmes at the University of Washington and his colleagues have developed a nonculture method to detect this strain in men with gonococcal urethritis. This technique, called DNA-hybridization, is less expensive than culturing the organism in a laboratory and would be useful for epidemiologic studies of gonorrhea in Third World countries. Dr. Holmes and his colleagues have also developed a rapid and sensitive test to identify penicillinase-producing gonococci in urethral fluid from infected men. This inexpensive method, called the fluorescent spot test, may be valuable in determining appropriate treatment for these patients.

Penicillin-resistant gonococci that do not produce penicillinase and are relatively common in the Far East have caused a few outbreaks in the United States. Dr. Sparling at the University of North Carolina and his colleagues recently reported a large outbreak in North Carolina. Although it was brought under control by use of another antibiotic and careful case-finding efforts, this event emphasizes the increasing problems associated with drug-resistant organisms.

Increasing drug resistance demonstrates the urgency of developing a vaccine against gonorrhea. However, vaccine development is hampered by the complexity of the gonococcus and by the fact that the organism only infects humans so no animal model can be used to test candidate vaccines.

The gonococcus has several structures on its surface that differ chemically from strain to strain and affect the organism's ability to attach to body tissues, to produce infections of varying severity, and to evade host defenses. Scientists have been searching for surface components, or antigens, common to all gonococci. Such an antigen could be used in a vaccine that would protect against all pathogenic (disease-causing) strains. NIAID grantee Dr. Janne Cannon, University of North Carolina, has identified an outer membrane antigen that appears common to all pathogenic strains and may be a potential vaccine candidate.

Chlamydial Infections

According to a report by a NIAID study group, an estimated three to four million Americans suffer from a broad spectrum of infections caused by Chlamydia trachomatis. It is one of the most common sexually transmitted pathogens in the United States, and contributes significantly to the the increasing number of women who experience ectopic pregnancy or involuntary sterility. Infants born to infected mothers are at risk of developing eye infections and pneumonia.

To show how widespread chlamydial infections are, Dr. William McCormack, currently at Downstate Medical Center, in Brooklyn, New York, and colleagues at Harvard University in Boston and at Brown University in Providence, Rhode Island, conducted a study of women college students. The study was supported by the NIAID and the National Institute of Child Health and Human Development (NICHD).

Chlamydial infections were documented in 4.9 percent of 431 women visiting the gynecologist in the student health service of a large university. The organism was not detected in any of the sexually inexperienced women in this group. Among those who were sexually experienced, the evidence of chlamydial infection in the genital tract increased in relation to the number of lifetime sexual partners only in women using nonbarrier methods of contraception. The study also showed that black women were considerably more likely than white women to be infected.

NIAID grantee Dr. Jones at Indiana University School of Medicine and his colleagues at the Marion County (Indiana) Health Department determined the prevalence of rectal chlamydial infection in 1221 women (5.2 percent) and of pharyngeal infection in the women (3.2 percent) and in 706 heterosexual men (3.7 percent) at risk for genital infection. The presence of rectal chlamydial infection in the women correlated with concurrent genital infection and may be important in the transmission or persistence of the infection. Recovery of C. trachomatis from the pharynx was not associated with symptoms. In women, but not men, pharyngeal infection was associated with a history of oral-genital sex.

Despite several studies that have documented prevalence rates as high as 30 percent in women, routine screening tests for chlamydial infections are rarely performed. Complicated tissue culture techniques have made such screening impractical. A major goal of NIAID-supported chlamydia research has been to improve diagnostic techniques.

A new technology, the ability to create monoclonal antibodies, has enabled grantees of the NIAID and the National Eye Institute (NEI) to develop a rapid diagnostic test for C. trachomatis. Dr. Walter Stamm and colleagues at the

University of Washington, in collaboration with Dr. Milton Tam of Genetic Systems in Seattle, developed a monoclonal antibody highly specific for a chlamydial antigen. When coupled with a fluorescent dye, this antibody can be used to test secretions obtained directly from patients and gives results within minutes rather than days.

NIAID intramural scientist Dr. Thomas Quinn compared the fluorescent antibody test with tissue culture techniques in a study of 1240 patients conducted with colleagues at The Johns Hopkins University in Baltimore. The antigen-detection test proved to be rapid, sensitive, and inexpensive. This study also demonstrated the importance of screening populations for chlamydial infections. Of 150 women treated with antibiotics for pelvic inflammatory disease, 14 percent were still infected with C. trachomatis after treatment. Inadequate diagnosis and treatment of patients such as these may increase the risk of tubal scarring and infertility due to chlamydial infection.

In Dr. Quinn's study of asymptomatic pregnant women, screening detected chlamydial infections in 16 percent. Since chlamydial infection during pregnancy may result in neonatal infection in 50 to 60 percent of infants, routine screening of high risk populations should be considered. In a study of 100 neonates with conjunctivitis, Dr. Quinn and colleagues at The Johns Hopkins University found that the eye infections were caused by C. trachomatis in 46 babies. In 19 percent, the chlamydia infection persisted after standard antibiotic treatment. This study emphasizes the need for careful follow-up and improved treatments.

Dr. Holmes and other NIAID grantees at the University of Washington in Seattle have shown the effectiveness of a two-step approach to screen women for genital chlamydial infection. This approach involves linking the fluorescent antibody test for chlamydial infections to the Pap (Papanicolaou) smears that millions of women undergo routinely each year. By screening Pap smears for specific patterns suggestive of chlamydial infection and then testing duplicate smears from those patients to confirm the infection, Dr. Holmes and his colleagues detected 76 percent of the chlamydial infections in a high-risk population.

In an effort to produce better diagnostic tests, NIAID grantee Dr. Stanley Falkow at Stanford University in Stanford, California, has developed probes to detect genetic material of C. trachomatis. In collaboration with Dr. Quinn, Dr. Falkow has developed a way to use these probes in order to detect chlamydia directly on Pap smears. The test appears to be as accurate as a culture or the immunofluorescent antibody test, but further development is required before it is generally available.

The technique of producing monoclonal antibodies has enabled scientists not only to develop improved diagnostic tests, but also to classify different types of C. trachomatis according to specific markers on the organism. Dr. J. Thomas Grayston at the University of Washington in Seattle, supported by the NIAID and the NEI, found that monoclonal antibody typing is simpler to perform and more precise than other methods. It allows easy differentiation between closely related types, thus facilitating epidemiologic investigations and studies of how the organism produces disease. In other studies with monoclonal antibodies, NIAID intramural scientist Dr. Harlan D. Caldwell has identified the major outer membrane protein of C. trachomatis that may be useful as a possible component of a chlamydia vaccine.

Genital Herpes

Genital herpes is a recurrent contagious viral disease usually spread by sexual intercourse. From 6 to 20 million episodes (either new infections or reactivations) are estimated to occur each year in the United States. Genital herpes can be particularly serious for women, who often experience more severe initial symptoms than men and whose risk of cervical cancer increases at least fourfold. Babies born to women with herpesvirus present in the birth canal risk acquiring a severe and sometimes fatal infection.

Dr. Nahmias, NIAID grantee at Emory University, is studying the epidemiology of genital herpes to learn more about how the disease is transmitted and who is at risk. Using monoclonal antibody techniques, he has developed a test that is suitable for screening large numbers of blood samples to identify specific types of herpesviruses.

Using this test, Dr. Nahmias and his colleagues screened blood samples from 2475 adults in different age groups. Their results showed that genital herpes was much more common in blacks than in whites ten years ago, but the incidence in whites is rising rapidly. Many individuals with antibodies to herpesviruses in their blood did not remember having had a herpes infection.

In a study of genital herpes patients at a sexually transmitted diseases clinic, Dr. Nahmias and his colleagues discovered that at least 38 percent of the patients were infected by partners with no symptoms and no lesions. Others were infected by partners with such mild clinical disease that the lesions were not recognized as being genital herpes.

Similar evidence of the frequency of asymptomatic infections was obtained in a study of pregnant women. Only 3 percent of the women admitted to having had genital herpes, but more than half had blood tests indicating prior infection.

Herpes infection in pregnant women is also being studied by Dr. Lawrence Corey, University of Washington in Seattle. He reports that women with primary herpes infections acquired during pregnancy have more asymptomatic viral shedding in the cervix and are more apt to begin labor earlier and deliver lower birthweight infants than women with recurrent herpes. This study is discussed in greater detail in the separate report on maternal and child health.

Although no cure for genital herpes is available, oral acyclovir has been approved for the treatment of initial episodes and treatment or suppression of frequent recurrent episodes. The drug was proved effective in extensive NIAID-supported clinical trials. In continuing studies of the drug, Dr. Corey has shown in homosexual men with herpes-caused rectal inflammation that 10 days of oral acyclovir treatment will decrease viral shedding and speed healing.

Cytomegalovirus Infections

Another member of the herpesvirus family, cytomegalovirus (CMV), is the leading cause of congenital infection and a common cause of life-threatening illness in immunosuppressed persons. Several NIAID-supported studies by Dr. Hunter Handsfield and his colleagues at the University of Washington in Seattle support the hypothesis that CMV is sexually transmitted.

They and others have found evidence that CMV infection is common in homosexual men, perhaps transmitted by anal intercourse, and is associated with an immunodeficiency that is unrelated to AIDS virus infection. CMV shedding is intermittent and inversely correlated with age. The virus is most frequently found in semen.

In studies documenting heterosexual transmission of CMV, Dr. Handsfield observed that young CMV-infected women who also had chlamydial infections shed more virus and presumably were more likely to transmit CMV infection.

The evidence that women of child-bearing age will acquire primary CMV infection by sexual contact has important public health consequences since primary infection during pregnancy is likely to cause more serious congenital infection.

Other NIAID-supported research on CMV infections is described in the separate report on mental retardation.

Syphilis

In 1984, about 28,000 cases of syphilis were reported in the United States, down sharply from the number reported three years ago. The decline has been most significant among homosexual men, who account for more than half of the reported cases. This decline may be due in part to changing sexual practices as a result of concern about AIDS.

Although syphilis is treatable, physicians believe that many patients remain undiagnosed and untreated. In general, about one-third of untreated patients will develop late syphilis, which can affect any organ of the body including the heart and the brain.

Diagnosis of syphilis generally involves microscopic examination of fluids from syphilis sores. This requires using a special technique called darkfield microscopy to identify the bacterium that causes the disease. Results can depend on the skill of the clinician in obtaining a specimen that contains the bacterium and the expertise of the microscopist in identifying it. Diagnostic blood tests are also used, but they do not give a positive result until the infection has been established for three to four weeks.

The ability to create monoclonal antibodies has enabled NIAID grantees to develop a simple and accurate test for early syphilis. Dr. Edward Hook and his colleagues at the University of Washington in Seattle have developed fluorescent monoclonal antibodies that react with several important antigens of the syphilis-causing bacterium. They collaborated with scientists at the Provincial Laboratory of Public Health, Edmonton, Alberta, to compare results of this new diagnostic test with those tests currently in use. They showed that the new test has the potential to provide a convenient, accurate means for definitive diagnosis of genital ulcer disease by health care personnel who do not have access to darkfield microscopy.

Other Sexually Transmitted Diseases

Group B streptococci (GBS) colonize the vagina and rectum of 20 to 35 percent of normal healthy young women; the risk of being infected rises with increasing sexual activity. Newborns exposed to GBS during passage through the mother's infected birth canal are at risk of serious illness. NIAID research on GBS is discussed in the separate report on mental retardation.

Genital warts, or condyloma acuminatum, are caused by the human papilloma virus (HPV), which can be sexually transmitted. Evidence indicates that genital warts are more common than genital herpes. NIAID grantee Dr. King Holmes reported that of 400 randomly selected women patients at a sexually transmitted diseases clinic, 45 percent had asymptomatic HPV infections.

Genital warts are most severe in immunosuppressed persons, homosexual men, and pregnant women. Warts enlarge during pregnancy and may cause hemorrhage or obstruction during delivery. Infants born to infected mothers are at risk of developing laryngeal papillomatosis (tumors in the throat). In addition, two of the 18 types of HPV have been clearly associated with both cervical and anogenital cancer.

NIAID is supporting a multi-center study to test the effectiveness of interferon as a treatment for patients with genital warts. Drs. Richard Reichman, University of Rochester in Rochester, New York; Richard Whitley, University of Alabama in Birmingham; Gerald Krueger and Spotswood Spruance, University of Utah in Salt Lake City; have reported that interferon injections benefit some patients. Their studies are continuing.

Chancroid, caused by Haemophilus ducreyi, is a sexually transmitted disease characterized by genital ulcers. It was once one of the six classic venereal diseases, but ceased to be a major problem in industrialized countries after sulfonamides became available for treatment. However, chancroid has continued to be a major problem in developing nations, where accurate diagnosis can be difficult in areas without extensive laboratory facilities. Dr. Sheila Lukehart, a NIAID grantee at the University of Washington in Seattle, in collaboration with scientists at the University of Texas Health Science Center at Dallas, has developed a monoclonal antibody that is specific and highly reactive and that may facilitate rapid identification of the organism.

National Cancer Institute

Approximately 80 percent of all pre-malignant and malignant cervical cancers are known to contain human papillomavirus (HPV) DNA. Over 40 types of HPV exist, only a few of which are associated with cervical cancer. Type 16 appears to be found in various stages of cervical dysplasia (the presence of abnormal cells), called "flat warts", as well as in carcinoma-in-situ (a small cancer that has not spread) and invasive cancer. Type 18 HPV is found in invasive cervical cancer and occasionally in precancerous genital tract abnormalities. Scientists are particualarly interested in determining whether these viruses are responsible only for benign conditions, such as genital warts, or are also playing a role in the development of cancer.

A number of recent studies have suggested that some strains of HPV, those that cause genital papillomavirus infections, may be associated with increased risk for cervical and other genital tract cancers. Dr. Wayne D. Lancaster of Georgetown University, Washington, D.C., is one of a number of NCI grantees studying the possible link.

Recently, Dr. Lancaster and co-workers found identical HPV genes in both the primary tumors and metastases of cervical cancer patients. They reported that samples of cancerous tissue from eight of 13 patients with cancers of the uterine cervix contained DNA from HPV-16. Another five tissue samples contained viral DNA closely related to HPV-16. Significantly, in six patients, cervical cancer cells from lymph nodes contained the same viral DNA. This study showed that HPV genes are associated with the cancer cells, and that the cancer cells that spread also carry the viral genes.

Additional research is critical for determining whether these papillomaviruses play a role in converting benign genital warts into cancer cells. Because related papillomaviruses of a number of animal species, including sheep, rabbits and cattle, convert normal animal cells to cancer cells in the laboratory, many scientists believe some HPV viruses may play a role either in initiating or maintaining cancerous changes in humans. However, because the human viruses have never been grown successfully in the laboratory, they are difficult to study.

Drs. Peter M. Howley and C. Richard Schlegel, intramural NCI researchers, are leading a team of scientists trying to analyze the HPV viruses associated with cervical cancer and identify their potential mechanisms of action. The scientists have found that cell lines derived from human cervical cancer tissues contained HPV-16 or HPV-18 DNA. Using the tools of recombinant DNA technology to study the viral genes, the scientists have learned that the viral DNA is making an RNA message in several of the cell lines; in other words, the viral gene is actively functioning in the cells. The scientists have identified the position where the viral DNA inserts itself into the human cellular genes in one of the cell lines, and are now analyzing the DNA units surrounding these viral genes. They also are working to make full-length clones of the messenger RNA's expressed by the viral genes, and are developing antibodies to the viral gene products (proteins) made by the human cells.

These initiatives will be important to development of more sensitive techniques for diagnosing and treating cervical cancer.

National Institute of Neurological and Communicative Disorders and Stroke

Central nervous system infection occasionally results from contagious agents that are sexually transmitted. In addition, some of these agents hide out in the peripheral nervous system between episodes of active infection.

Research on sexually transmitted diseases supported by the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) focuses on how the nervous system is involved in these illnesses. NINCDS grantees recently added to the understanding of diseases caused by the herpes simplex virus and the closely related cytomegalovirus. Findings related to AIDS are described in a separate report.

Herpes simplex

After herpes lesions clear up, the herpesvirus becomes latent, sequestered in clusters of nerve cell bodies near the spinal cord. Previous research has shown that the latent virus is not dormant. This year, in studies using mice, NINCDS grantee Dr. Richard Tenser at the Milton S. Hershey Medical Center of the Pennsylvania State University in Hershey found that while hidden, the herpesvirus executes some of the initial steps of its reproduction cycle. This finding suggests that it may be possible to kill the virus by interfering with these steps.

Dr. Tenser also reported that herpesvirus strains lacking an enzyme called thymidine kinase are less likely to set up latent infections in nerve cells. Further studies are planned to determine this enzyme's role in the disease process.

Dr. Nigel Fraser, an NINCDS grantee at the Wistar Institute in Philadelphia, Pennsylvania, has been studying the latency of the Type I herpesvirus in mice. During periods of active infection, when many new virus particles are being made, the virus's genetic material is arranged in a line resembling a piece of string. Dr. Fraser learned that when the virus is in the latent stage, and few if any new virus particles are generated, the ends of the virus's DNA strands join together forming a ring. He is trying to determine whether it is this circular shape that prevents the virus from reproducing.

Using probes manufactured by genetic engineering techniques, Dr. Fraser has discovered that, during reactivated herpes infections, the virus can be found not only in neurons but also in cells that surround and support the neurons. In latent infections, however, only neurons themselves harbor the virus. Dr. Fraser is now studying how neurons and the virus interact to sustain latent infections.

Many studies suggest that the herpes simplex virus is carried from the peripheral nervous system to the central nervous system through long nerve cell fibers called axons. How the virus initially enters the axons of peripheral nerve cells is unknown. NINCDS grantee Dr. Jeannette J. Townsend, at the University of Utah School of Medicine in Salt Lake City, has developed markers to track the virus in mice as it enters and is transported within axons. This research may suggest ways to prevent the virus from entering the nervous system.

NINCDS intramural scientist Dr. John R. Martin this year developed a model for studying latency and reactivation of the Type 2 herpesvirus in mice. When herpes is latent, the nervous system harbors the virus, but the genital area is virus-free. Dr. Martin showed that when mice with latent genital herpes are given an immunosuppressive drug, the virus is reactivated and can be recovered from the genital tract as well as the nervous system. This model should help scientists learn more about the types of cells the herpesvirus infects and the pattern of disease it produces.

Cytomegalovirus

Dr. James Bale, an NINCDS grantee at the University of Iowa Hospital and Clinics in Iowa City, reported last year that cytomegalovirus affects the ability of certain immune cells to perform their disease-fighting tasks. This year, using probes made by genetic engineering techniques, Dr. Bale undertook to determine at a molecular level why these immune cells don't work. Such probes may enable him to discover the stage of infection at which the cells' disease-fighting functions become impaired.

NINCDS grantee Dr. Michael Graves of the University of California at Los Angeles found for the first time that cytomegalovirus can be latent in the nervous system. Scientists knew that the virus could be latent in the spleen and perhaps in certain white blood cells, but did not know it could hide in the nervous system until Dr. Graves isolated latent virus from the peripheral nervous system of the mouse. The virus appears to hide not in the nerve cells themselves, but in the surrounding, supporting cells.

National Institute of Child Health and Human Development

The National Institute of Child Health and Human Development (NICHD) is currently investigating relationships between contraceptive methods and diseases that are sexually transmitted or associated with sexual activity. NICHD also supports research on maternal infection and its relationship to preterm and/or low birth weight deliveries as well as congenital defects in the newborn.

Barrier methods of contraception include the diaphragm; spermicidal foams, creams, and jellies; and the condom. After a long period of declining use beginning in the early 1960's, barrier methods have become increasingly popular in recent years. These methods have not been implicated as a cause of major illness or disability in users, with the possible exception of cystitis. In fact, evidence has been available for years that spermicides inhibit a variety of agents that cause sexually transmitted diseases, but this important noncontraceptive health benefit has never been adequately evaluated or quantified. NICHD is currently supporting a clinical trial to study the issue.

In preparation for the clinical trial, NICHD grantee Dr. William Louv at the University of Alabama in Birmingham completed microbiolgical testing and determined the concentration at which commercially prepared spermicides inhibit N. gonorrhea and C. trachomatis, the most common sexual disease agents. Chlamydia is the most common cause of pelvic inflammatory disease. The scientists have evaluated and used various methods of detecting chlamydia because it is difficult to grow in the laboratory.

Approximately 800 women with relatively high rates of both gonorrhea and chlamydia have been registered for the trial, and the followup rate has been approximately 90 percent. Women in the study group use spermicide, and those in a control group use a placebo preparation; all use an additional means of contraception as well. Preliminary analyses indicate that the risk of sexually transmitted infection is lower among spermicide users than those in the control group, but the magnitude of the effect on the two organisms has not yet been determined.

If infection is an important precursor of preterm birth, then the ways in which cervical/vaginal seeding with the bacteria occurs is of considerable importance. Sexual transmission is an obvious possibility for some organisms, and the relation of the frequency of coitus to pregnancy outcome is therefore of considerable interest. In two separate analyses recently completed by NICHD epidemiologists, no important association was found between frequency of coitus during pregnancy and cervical or vaginal infections.

Cytomegalovirus (CMV) appears to be the most common perinatal viral infectious disease. Although CMV rarely produces noticeable symptoms in healthy children or adults, its effects in utero can be devastating. It can involve the brain, eyes, bone, heart, nervous system, or liver, causing severe birth defects or death. CMV is the most common viral cause of mental retardation, affecting more than 3,000 infants per year. No specific treatment is currently available.

CMV has been found to be present in 3 to 15 percent of pregnant women, depending on their age, socioeconomic status, and duration of gestation. It is unknown how CMV infections are transmitted to the developing embryo or how congenital defects are produced. To gain information applicable to humans, NICHD-supported researcher Dr. John T. Baskar at the University of North Carolina at Chapel Hill is studying CMV infection in a mouse model. He is examining the types of tissues that are adversely affected, the stage of gestation at which defects occur, and the possibility that infected sperm may be the mode by which the virus is transmitted to the ovum. These studies should provide information on the mechanisms underlying fetal maldevelopment and the mode by which viruses are transmitted from mother to fetus through the genital tract.

SPINAL CORD INJURY

Obligations

	1983	1984	1985	1986 Appropriation	1986 Available After Sequestering	1986 Revised Estimate	1987 Estimate
Public Health Service:							
National Institutes of Health:							
National Institute of Neurological and Communicative Disorders and Stroke............	18,556,000	19,719,000	21,511,000	23,531,000	22,519,000	22,000,000	21,767,000
Total, NIH..........	18,556,000	19,719,000	21,511,000	23,531,000	22,519,000	22,000,000	21,767,000

NATIONAL INSTITUTES OF HEALTH

National Institute of Neurological and Communicative Disorders and Stroke

SPINAL CORD INJURY

Spinal cord injury resulting in loss of sensation and paralysis is one of the most tragic medical problems facing our Nation. Approximately 10,000 new spinal cord injuries occur each year in the United States, and these injuries strike hardest at the Nation's youth. Central Nervous System Trauma Report, 1985, prepared by Drs. Donald Becker and John Povlishock at the Medical College of Virginia in Richmond under a research contract from the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), observes: "Spinal cord injury is a disease of young people; the majority of injuries occur in the second and third decades, with the vast majority of victims being young males."

Survival following injury has been greatly enhanced by improved medical and surgical care. The number of spinal cord injury victims living in the United States is now estimated to be between 250,000 and 500,000. Their need for long-term special services each year costs society some $2 billion.

Within the Federal Government, the NINCDS leads the research attack on this problem, supporting extensive studies on biomedical aspects of spinal cord injury and nervous system repair, regrowth, and replacement. This research program has three major goals:

- to understand what changes take place within the spinal cord immediately after injury, and to find ways to prevent further damage.
- to understand the mechanisms of nerve growth and regeneration as a step toward reversing paralysis and restoring function.
- to supplement or replace lost neurological function through the development of neural prostheses.

Several other Federal agencies are also working to improve the outlook for victims of spinal cord injury. Rehabilitation projects are principally the responsibility of the National Institute of Handicapped Research, Department of Education. Leadership in the delivery of health-care services is the focus of the Public Health Service's Health Resources and Services Administration. A coordinated national effort is in place and includes continuous staff interaction, collaborative planning, and formal interagency committees.

Limiting Damage, Enhancing Recovery

Because of strong evidence that the first few hours after injury--the acute period--are critical in preventing further damage to the spinal cord and further loss of function, the NINCDS has established a national program of Spinal Cord Injury Clinical Research Centers to focus on this phase of injury. The Institute supports five such centers, located at Yale University in New Haven, Connecticut; Ohio State University in Columbus; the Medical University of South Carolina in Charleston; New York University in New York City; and the University of Texas Health Science Center at San Antonio.

Investigators at these centers are engaged in studies to understand the complex series of events that begin in the injured spinal cord immediately after trauma and are believed to continue for several weeks. A crushed or bruised cord is not completely severed, and may initially retain function; but this residual function may be lost as the body responds to injury by releasing substances that control pain, swelling, and bleeding. Studies are under way to evaluate treatments aimed at reducing this secondary damage.

Led by Dr. Eugene Flamm at the New York University Center, teams of scientists there, at the Yale University Center, and at Baylor University in Houston, Texas, this year completed a pilot study testing naloxone, a drug that in animal studies has shown promise in improving blood flow and functional recovery during the first weeks following injury.

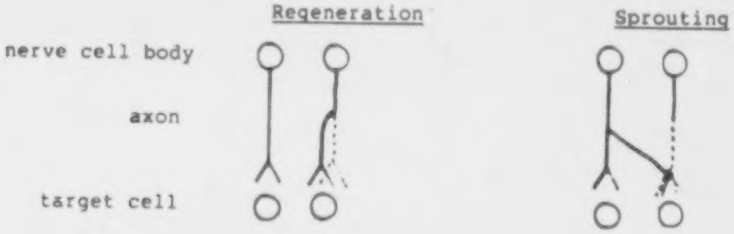
The investigators administered variable doses of naloxone to 29 patients with moderate to severe spinal cord injury. Some received only low doses, and others relatively high doses within the range found in animal studies to be effective in reducing secondary cord damage. Naloxone, which blocks the action of pain-killing substances, was tolerated by all but one patient, who experienced pain severe enough to halt treatment. Three of the nine patients who received high doses regained some sensation or motor strength within 36 hours of treatment; patients given low doses showed no improvement, which suggested a dose-related effect. These results demonstrated that naloxone has minimal side effects and may improve the neurological condition of victims of spinal cord injury during the period shortly after injury.

To verify these encouraging findings, the NINCDS has begun a nationwide clinical trial to evaluate naloxone and the steroid methylprednisolone (a drug that has produced results similar to naloxone in animal studies) in patients with severe spinal cord trauma. This is a multi-institutional study under the leadership of Dr. Michael Bracken at Yale University.

Regenerating Damaged Nerve Cells

NINCDS-supported studies using an insect model have shown that under laboratory conditions damaged nerve cells (neurons) of the brain and spinal cord can regenerate and repair themselves as do skin and muscle nerve cells. After injury, a portion of the axon--the long fiber that arises from the nerve cell body--undergoes "budding," and numerous growth cones form above the injury site. These growth cones extend in several directions. Eventually one becomes the principal outgrowth, extending until it recognizes, reaches, and reconnects with a target. The growing nerve must make the correct connections with specific target nerves for function to be restored.

Another form of neuronal regrowth is "sprouting." In sprouting, an uninjured neuron responds to injury or loss of a neighboring neuron by producing an outgrowth that extends to the neighboring neuron's target.



Regeneration and sprouting of damaged spinal cord nerve cells appear to hold the best biological hope for conquering paralysis. The NINCDS supports an extensive range of laboratory studies that address the complexities of neuronal regrowth.

Major goals in regeneration research are to identify the body's own agents that promote neuronal growth and to learn how to regulate the body's own growth factors to promote regeneration. NINCDS grantee Dr. Katherine Kalil, at the University of Wisconsin in Madison, has been working with growth associated protein-43 (GAP-43), a substance appearing only during nerve cell development. She has shown this year that injured nerves in the immature hamster central nervous system will regenerate when GAP-43 is present. In other work, Dr. Keith Crutcher, an NINCDS grantee in Salt Lake City at the University of Utah, recently found a substance that resembles nerve growth factor in the rat brain as it responds to injury. Learning how to regulate proteins like GAP-43 and the nerve growth factor-like substance may someday enable scientists to induce mature injured neurons to regenerate or uninjured neurons to sprout in response to nervous system injury.

Within the central nervous system there are more neurons than needed for normal body function. Scientists refer to some of these extra neurons as "silent," and in their search for ways to compensate for neural loss after injury are trying to recruit silent neurons to replace injured ones. Dr. Lillian M. Pubols, an NINCDS grantee at Good Samaritan Hospital and Medical Center in Portland, Oregon, this year used mechanical and electrical stimulation of nerves to identify silent neurons in the spinal cord. This identification provides the foundation neuroscientists need for studies of silent neuron manipulation.

For example, silent neurons may be induced to sprout. Dr. Jerome Sutin, an NINCDS grantee at Emory University in Atlanta, Georgia, recently demonstrated that sprouted neurons from the rat jaw are functional. Using electrical stimulation, Dr. Sutin showed that sprouted neurons responded to stimulus by causing the muscle to contract.

Restoring Lost Function

Implanting neural tissue into the severed spinal cord is a new and potentially powerful method to restore lost function. In this past year, there were major advances in implant studies at three NINCDS-supported laboratories:

o At the Medical College of Pennsylvania in Philadelphia, Dr. Allen Tessler has found that rat fetal tissue implanted in the rat spinal cord immediately after injury remains viable three months later, and that the neurons within the implant develop normally.

o Dr. Paul J. Reier, at the University of Florida in Gainesville, has shown that rat neural tissue can be implanted successfully into the injured rat spinal cord between 7 and 14 days after injury. This is an important finding because in cases of human spinal cord injury there would generally be a delay before implantation procedures could take place.

o Dr. Richard P. Bunge, at Washington University in St. Louis, this year was the first to implant cultured neurons and their associated support cells into the rat spinal cord and have the implants remain viable. If these implants can also be shown to restore function, this method would establish cultured cells as an invaluable source of implant material. Because cultured cells can be propagated, a single donor could supply material for multiple implants.

Scar tissue often presents a barrier to neuron regeneration and reconnection. Dr. Jerry Silver, in the NINCDS-supported regeneration research program at Case Western Reserve University, Cleveland, Ohio, recently found that when small filters covered with rat fetal astrocytes (a type of neural support cell) are inserted into a fresh wound in the rat spinal cord, bleeding is diminished and scar tissue formation repressed. The insert also serves as a platform or guide for the regenerating neurons to follow in seeking correct reconnections. Future studies are planned to see whether beneficial effects occur when insertion is delayed, as would be the case for accident victims.

Promising advances are also being made in encouraging regenerating nerves to make functional connections. This year Dr. Jeffery Denberg, an NINCDS grantee at the University of Iowa in Iowa City, found through studies of the insect neuromuscular system that specific marker molecules in muscle membranes may guide neurons to correct targets. Dr. Denberg is attempting to identify these markers using monoclonal antibodies, which are capable of distinguishing molecules with subtle chemical differences. Success in these studies may lead to methods for restablishing correct connections in the injured nervous system.

At the NINCDS-funded Spinal Cord Injury Clinical Research Center at New York University, Dr. Andrew Blight demonstrated this year that in paralyzed cats a small percentage of axons in the severely injured spinal cord remain functional, although they work abnormally. This offers hope on two fronts. First, it may be possible through implants or drug treatment to repair these axons so they function normally. Or it may be possible to recruit silent axons as guides for regenerated or implanted tissue to follow through the scar tissue.

Neural Prosthesis Program

Implantable electronic devices can help compensate for lost sensory and motor function and allow the paralyzed patient to regain some measure of muscle control. The NINCDS Neural Prosthesis Program focuses on overcoming basic problems involved in the development and use of these devices.

Among the most critical problems facing patients with spinal cord injury are those involving control of the urinary bladder. Residual urine can cause bladder infections, which in turn can generate kidney disorders. A leading cause of death among spinal cord injury victims, according to this year's Central Nervous System Trauma Report, is renal failure.

NINCDS grantee Dr. Emil Tanagho, at the University of California, San Francisco, has developed a surgically implantable bladder pacemaker that the patient can activate with a hand-held remote control unit. The pacemaker stimulates nerves controlling the bladder, sending signals that contract the bladder muscle and expel stored urine. The device is currently implanted in nine patients, one of whom, a paraplegic, has used it for nearly three years without major complication. Further work in perfecting the system will focus on reducing the amount of residual urine remaining in the bladder after voiding.

A totally implantable receiver-stimulator to activate paralyzed hand muscles was developed this year at Case Western

Reserve University by NINCDS grantee Dr. Hunter Peckham. The device will soon be evaluated in humans.

With support from an NINCDS research contract, Dr. Tom Kicker at Case Western Reserve University this year began work on a new generation of reliable and long-lasting electrodes for implantation into paralyzed muscles. Two other NINCDS research contract studies are related. Dr. Theodore Beck, at Electrochemical Technology Corporation, Seattle, Washington, continues to evaluate materials used in such electrodes, while Dr. William F. Agnew, at Huntington Medical Research Institutes, Pasadena, California, pursues the development of safe techniques for activating neurons by electrical stimulation.

Research Outlook

Understanding the mechanisms at work during and after spinal cord injury and developing strategies to prevent and reverse paralysis are among the most exciting research problems in the neurosciences today. The NINCDS continues to sponsor and stimulate research on spinal cord injury and regeneration, and to attract and train young investigators for productive work in these fields of investigation.

Encouraging results have emerged in the areas of preventing secondary injury, inducing regeneration of injured axons, sprouting of spared axons, and implantation of neural tissue to replace injured neurons. Scientists now face the challenge of bringing together these various successes to promote true functional recovery for spinal-cord-injured patients.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

SPINAL CORD INJURY

There were an estimated 12,000 patients hospitalized in short-stay hospitals in 1984 who had a first-listed diagnosis of spinal cord injury. About 67 percent of these patients were in the 15-44 year age group and 67 percent were males. The average length of stay for both sexes was 24.3 days. In addition to the 12,000 first-listed diagnoses of spinal cord injury, there were an additional 11,000 secondary diagnoses of spinal injury. Due to the fairly high relative standard error associated with such a low number of discharges, care should be taken in comparing the age and sex ratios to the 1983 data.

STROKE

Obligations

	1983	1984	1985	1986 Appropriation	1986 Available After Sequestering	1986 Revised Estimate	1987 Estimate
Public Health Service:							
National Institutes of Health:							
National Institute of Neurological and Communicative Disorders and Stroke.............	21,523,000	23,563,000	26,229,000	28,691,000	27,457,000	26,825,000	26,541,000
National Heart, Lung, and Blood Institute...	7,889,000	8,338,000	10,326,000	11,050,000	10,500,000	10,350,000	10,100,000
Total, NIH..........	29,412,000	31,901,000	36,555,000	39,741,000	37,957,000	37,175,000	36,641,000

NATIONAL INSTITUTES OF HEALTH

National Institute of Neurological and Communicative Disorders and Stroke

STROKE

Interrupted blood flow to the brain lies behind the most widespread neurological problem in the United States today: stroke. Stroke affects nearly 400,000 Americans each year, about 150,000 of whom die from complications. It is the Nation's third leading killer. Survivors--a group now numbering 1.9 million in the U.S.--are often left with permanent disabilities that drain their energy, savings, and courage.

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) is the focal point within the Federal Government for research on the cause, treatment, and prevention of stroke. The Institute's stroke research program represents a diversity of studies by individual investigators in institutions across the country and teams of scientists in larger stroke research centers. The National Heart, Lung, and Blood Institute (NHLBI) also plays an important role in the national effort, primarily through its research on such major stroke risk factors as atherosclerosis and high blood pressure.

Evidence that this ambitious research effort is proving fruitful is the steady decline in the stroke death rate over the past decade:

Year	No. of Fatal Strokes	Rate per 100,000
1975	194,038	91.1
1977	181,934	84.1
1979	169,488	77.0
1981	163,504	71.3
1983	156,290 (provisional)	66.7
1984	153,890 (provisional)	65.5

Much of this decline has been attributed to improvements in the diagnosis and treatment of transient ischemic attacks (TIA's); to specific treatment for particular types of stroke immediately after the attack; and to increased public awareness of the dangers of stroke risk factors such as TIA's, high blood pressure, and diabetes. (TIA's or "little strokes" are warning signs of a major stroke that disappear completely within 24 hours and often within minutes. TIA symptoms include tingling or weakness in a limb or on one side of the face, loss of strength in a limb, difficulty with speech, or temporary blindness in one eye or both.)

Nevertheless, stroke remains an $8 billion-a-year national burden. As described later in this report, a notable advance toward easing this cost burden was achieved this year with completion of an NINCDS-supported international collaborative study to assess a widely used neurosurgical procedure thought to be useful in preventing impending stroke.

What is a Stroke?

A stroke is a sudden loss of brain function caused by decreased blood flow to a part of the brain. Some strokes are minor; others may quickly cause death. Usually a stroke is brought on by one of four events: (1) thrombosis--a blood clot forms within a blood vessel of the brain or neck; (2) cerebral embolism--a blood vessel in the brain is blocked by a piece of clot or other material carried through the circulation from some other part of the body, often from the neck blood vessels or heart; (3) stenosis--an artery supplying blood to the brain becomes severely narrowed, usually as a result of atherosclerosis; or (4) cerebral hemorrhage--a cerebral blood vessel ruptures, with bleeding into the brain tissue or spaces surrounding the brain.

The major cause of stroke is the blockage of a blood vessel in the brain by a clot. Although such blockage does not usually cause death, the large number of strokes caused by blockage accounts for about 75 percent of all stroke deaths. The next largest category of stroke deaths is hemorrhage, which causes about 15 percent of the fatalities.

Stroke is usually the culmination of progressive disease that may extend over many years and that is rarely detected in a routine physical examination. In some cases, stroke gives no warning signs and takes its victims completely by surprise. Many attacks, however, can be prevented by heeding those warning signs and risk factors identified through stroke research.

The NINCDS Stroke Research Program

Over the past two decades, largely as a result of NINCDS's encouragement of investigators to study the problem of stroke, cerebrovascular disease has become a topic of research interest in many of the Nation's outstanding scientific institutions. Much of this research has been in the fundamental neurosciences related to the control of the cerebral circulation and metabolism. This work is reinforced by Institute-sponsored programs that train scientists in the skills necessary for productive research in neurology, neurosurgery, and related fields. NINCDS programs are coordinated with the atherosclerosis and hypertension programs of the National Heart, Lung, and Blood Institute.

The EC/IC Bypass Study

This year, Dr. Henry J.M. Barnett, an NINCDS grantee at Canada's University of Western Ontario, announced that a common neurosurgical procedure--known as the extracranial/intracranial (EC/IC) bypass--was no more beneficial than nonsurgical therapy (drugs and aggressive hypertension control) in preventing stroke in high-risk patients. The EC/IC operation involves joining a scalp artery through an opening in the skull to the middle cerebral artery to supplement blood supply to a threatened area of the brain.

The finding was consistent regardless of the sex or age of the patient, the site or type of brain damage before surgery, the presence of prior stroke or functional impairment, the existence of other health problems such as diabetes or heart trouble, or a number of other potentially confounding factors that were studied. The results showed that EC/IC bypass was not any better than nonsurgical therapy in preventing stroke, reducing stroke-related deaths, or even limiting future stroke on the side of the brain where the operation was performed.

Dr. Barnett and colleagues concluded that in view of the risks inherent in surgery and in the absence of any benefit not available through nonsurgical treatment alone, the EC/IC bypass should no longer be performed as a preventive or therapeutic measure. This announcement culminated an 8-year international study to investigate the efficacy of the procedure.

The finding should have a marked impact on health care costs for stroke. In the United States, the estimated cost of an EC/IC bypass operation is $15,000. Since EC/IC surgery is the second most common operative procedure for stroke, the savings realized by eliminating this unnecessary surgery will be considerable.

The study also revealed that the surgery does not enhance recovery from a stroke occurring after the bypass is in place, nor does it reduce the frequency of transient ischemic attacks any more than a combination of drug therapy and hypertension control. The EC/IC study, which involved 63 centers on 4 continents, succeeded in setting an international standard for the evaluation of neurosurgical procedures.

Other Long-Term Studies

At the University of Virginia in Charlottesville, NINCDS grantee Dr. Neal Kassell is analyzing the results of a 7-year international study to determine the effects of early surgery for a ruptured brain aneurysm, a weak spot in an artery that can burst and interrupt brain blood flow. Aneurysms are responsible for most hemorrhagic strokes. Preliminary data analyzed this year indicate that early surgery--1 to 3 days after the rupture--results in better recovery than surgery 4 to 7 days later.

Since 1978, the NINCDS has supported community hospital-based stroke programs in Winston-Salem, North Carolina; Portland, Oregon; and Rochester, New York, that provide information about stroke care and recovery in a range of population settings.

Physicians in these programs have accumulated detailed records on 4,219 stroke patients and have analyzed various factors known to contribute to stroke.

This year, a team of scientists from the three programs analyzed data on patients with strokes due to blood clots, hemorrhage, and undetermined causes. The data revealed that increasing age and a history of cardiac disease or previous stroke affected the extent of recovery in patients whose stroke was caused by blood clot. For patients suffering a hemorrhagic stroke, level of consciousness when admitted to treatment was the only predictive factor for recovery. If the cause of stroke was not identified, a history of cardiac disease adversely affected the patient's ability to overcome the effects of a stroke.

Another long-term health study, the NINCDS-supported Framingham Study on Stroke, focuses on a closely monitored Massachusetts community, and is enabling scientists to test the profile of the high-risk stroke patient. This year, NINCDS grantee Dr. Philip Wolf and colleagues at Boston University in Massachusetts used the Framingham data to determine that hypertension--and to a lesser extent, cigarette smoking--is a risk factor for subarachnoid hemorrhage. The scientists also examined coronary heart disease as a precursor of stroke. The actual presence of coronary heart disease in a patient proved to be as strong a predictor of stroke as did five major coronary heart disease-risk factors combined (elevated systolic blood pressure, cigarette smoking, diabetes, elevated serum cholesterol, and enlarged left ventricle as measured by electrocardiogram).

Dr. Wolf's group also found that an elevated level of fibrinogen, a protein in blood plasma, was a risk factor for stroke and cerebrovascular disease. Patients with atrial fibrillation, a condition in which certain heart muscles contract irregularly, were found to have an increased risk of stroke as they grow older.

Clinical Research Centers

Cerebrovascular clinical research centers--now numbering 14 in university medical complexes across the U.S.--are a major strength of the NINCDS stroke research program. These centers are located at the University of Alabama in Birmingham; Duke University in Durham, North Carolina; Washington University in St. Louis, Missouri; the Mayo Medical School in Rochester, Minnesota; the University of Maryland in Baltimore; Cornell University Medical College in New York City; the University of Pennsylvania in Philadelphia; the University of Miami in Florida; Bowman Gray School of Medicine in Winston-Salem, North Carolina; Massachusetts General Hospital in Boston; the Oregon Health Sciences University in Portland; the University of Texas in Houston; the University of Tennessee in Memphis; and the Rush Presbyterian-St. Luke's Medical Center in Chicago.

These centers provide a stimulating environment for research on the causes of stroke. The disease process is becoming more clearly defined, and significant advances have been made toward identifying predisposing high-risk factors. Some of these factors are amenable to control measures that can prevent or delay cerebrovascular accidents in some patients.

At the Cornell University Cerebrovascular Research Center, Dr. William Pulsinelli has been exploring mechanisms of stroke damage. This year, he discovered in the rat brain that when he limited the stimulation certain nerve cells received from neurotransmitters, these cells were less damaged by reduced blood flow. This work indicates that neurotransmitter activity may affect the extent of nerve cell damage in a stroke attack.

Dr. Marcus Raichle and coworkers at the Washington University Cerebrovascular Research Center are using positron emission tomography (PET), a technology that produces computer-enhanced images of metabolic activity within the living brain, to study cerebral blood flow and metabolism. This year, Dr. Raichle scanned 4 patients with stroke-related muscle weakness on one side of the body. Two patients, whose scans showed slightly higher blood flow and oxygen metabolism in certain brain areas, recovered their strength; the patients with lower blood flow and oxygen metabolism remained weak. These preliminary findings indicate that PET might have the potential for identifying stroke victims whose neurological losses may be reversible.

At the the Mayo Clinic Cerebrovascular Research Center, Dr. Robert Wharen, Jr., and associates have found this year that directing short, intermittent pulses of laser light at brain blood vessels can reduce blood flow during surgery without damaging normal brain tissue. The technique can safely be used to help coagulate blood during the removal of vascular tumors, malformations, and aneurysms that can cause stroke.

Dr. Kenneth Wu at the University of Texas in Houston Cerebrovascular Research Center has been investigating how a blood clot (thrombus) forms. Recently he discovered that adding lymphocytes, a type of white blood cell, to a mixture of thrombus-producing blood platelets reduced the platelets' ability to promote clotting. If scientists can develop a practical way to use lymphocytes to control clotting in the brain, the incidence of thrombotic stroke may be reduced.

Applied Research

Magnetic resonance imaging (MRI) is a new noninvasive scanning technique that uses magnetism to produce pictures of the brain's anatomy and metabolism. At Baylor College of Medicine in Houston, Texas, NINCDS grantee Dr. R. Nick Bryan recently confirmed that MRI scanning is at least as sensitive as computed tomography (CT) scanning in detecting that a stroke has occurred, if not more sensitive. In addition, he found that a certain type of MRI scan can provide significantly more information about the effects of stroke than the CT scanner. This discovery enhances MRI's potential for becoming a diagnostic tool. Dr. Bryan is also using MRI technology to chart biochemical changes in the rat brain during experimentally produced stroke.

Dr. Hank Kung, an NINCDS grantee at the State University of New York in Buffalo, this year developed a series of radioactively labeled chemicals that can be used with various technologies for brain imaging. These chemicals will allow scientists to obtain diagnostic information about brain function in patients with abnormal cerebrovascular circulation. The chemicals will be suitable for wide clinical application, because they are readily prepared in kit form, are inexpensive, and deliver only small amounts of radiation to patients.

At the University of California in San Francisco, NINCDS grantee Dr. Yoshio Hosobuchi is continuing to test the effects of three related drugs--naloxone, naltrexone, and diprenorphine--on cerebral ischemia (blood deprivation to brain tissue) in the cat. Dr. Hosobuchi's research confirms that, properly administered, these drugs can partially reverse neurological losses due to stroke and can prolong survival in certain types of stroke.

Stroke Data Bank

The NINCDS-funded Stroke Data Bank, the first national computerized storehouse of stroke information, is continuing to collect clinical data to answer research questions about the characteristics and recovery of stroke patients. Participating centers at Boston University, Duke University, the University of South Alabama in Mobile, and the University of Maryland have now entered the main phase of data collection, with approximately 1,000 patients enrolled. Project scientists will continue to collect and analyze stroke information over the next 2 years.

The National Heart, Lung, and Blood Institute

Stroke is often a consequence of arteriosclerosis, particularly lesions affecting the cerebral blood vessels or the brain's major arterial feedlines. Many individuals at high risk of stroke have atherosclerotic lesions partially obstructing either or both carotid arteries, the principal ones supplying the head and neck. Recent developments in diagnostic techniques are making it possible to detect and evaluate such lesions in the neck vessels with very little risk or discomfort for the patient. One such technique, called ultrasonic duplex scanning, involves no risk at all. It combines conventional ultrasonic imaging and a technique that uses pulsed ultrasound to determine the speed of the blood flow in the vessel being scanned.

Dr. Donald E. Strandness, Jr., and colleagues, NHLBI grantees at the University of Washington and the Seattle VA Medical Center, evaluated the new technique in 135 patients, all of whom subsequently underwent conventional cerebral angiography, a technique that requires the injection of a contrast material into the patient's bloodstream so that the brain's blood vessels can be seen on x-ray. Duplex scanning correctly detected the presence of disease in 97 percent of the carotid arteries studied. Estimates of the degree of carotid narrowing from the duplex scan were sometimes at variance with the findings on cerebral angiography, especially if the degree of narrowing was 10 percent or less, but the agreement between the two techniques was good for high-grade lesions (ones with 50-99 percent occlusion).

Carotid artery lesions are often surgically accessible. Indeed, carotid endarterectomy (in which blood vessel obstructions are "reamed out") has become the second most commonly performed vascular operation (after coronary artery bypass) in the U.S. Currently some 93,000 such operations are being done each year--many of them "prophylactic" procedures in patients with carotid bruits (the abnormal sounds caused by turbulent blood flow in regions of partial obstruction) but no symptoms of cerebral insufficiency. Though surgery is considered the therapy of choice for patients with carotid lesions and transient ischemic attacks (TIAs) by some physicians, others point out that: 1) surgery sometimes precipitates strokes that the operation was supposed to forestall; 2) in some facilities surgery has produced unacceptably high morbidity and mortality rates; 3) the evidence is not clear that surgery is superior to medical management in most patients; and 4) only 15-20 percent of patients with TIAs are suitable candidates for surgery and patients with asymptomatic bruits are probably better off if managed medically or left alone.

Dr. Stephen C. Nicholls and coworkers, NHLBI grantees at the University of Washington, followed for four years 134 patients who had undergone carotid endarterectomy. Of these, 22 per cent experienced recurrent high-grade stenosis of the operated artery or arteries, the incidence of restenosis being substantially higher among female than among male patients. When restenosis occurred, it usually did so early (within 12 months of surgery), but no consistent pattern was observed between recurrent stenosis and symptoms subsequently experienced by the patients. The investigators concluded that reoperation to prevent subsequent TIA's or stroke probably was unjustified in patients whose first operation had not achieved long-term relief of carotid artery narrowing.

In patients with TIA's due to carotid artery disease, the main culprit is thought to be blood platelets, which aggregate on or in the vicinity of the carotid lesions, then break free, travel as platelet microemboli into the cerebral circulation, and plug smaller blood vessels. Though usually short lived, platelet microemboli can cause blood deprivation in brain tissues while they last and thus produce the TIA's. The keystone of medical management to prevent strokes in the highly susceptible-particularly those who have experienced TIAs--has been platelet antiaggregants, particularly aspirin. Aspirin is inexpensive, readily available, safe for most patients, and appears to be at least as effective as any other available antiaggregant. These drugs apparently work by blocking the production by platelets of a prostaglandin called thromboxane A_2, which stimulates the clumping of platelets and constricts bloodvessels. But such drugs can also impede the production in the blood vessel wall of another prostaglandin called prostacyclin, a "protective" substance with effects almost precisely opposite to those of thromboxane A_2. Fortunately, it appears to require higher doses of antiaggregants to stop prostacyclin production than thromboxane A_2 production, but the dosages needed to provide maximal protection against strokes are still uncertain.

Dr. Marion Barnhart and coworkers at Wayne State University have identified a number of individuals with what they have termed "sticky platelet syndrome" because their platelets aggregate more readily and form larger, longer lasting clumps than do those of normal persons. Many victims, though quite young, have a history of TIA's, stroke, angina, or heart attack; most also suffer from migraine headache. The investigators found that patients with the syndrome (which may be hereditary) respond well to antiaggregant therapy.

Research Outlook

Scientists who have been searching for new clinical insights into the puzzles posed by stroke are encouraged by the unequivocal results of the EC/IC bypass study, the development of new forms of brain-imaging technology, and the steady elucidation of stroke risk factors. The NIH is working to maintain this momentum in stroke research and to attract more investigators into the field.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

STROKE

Based on the 1984 data from the National Hospital Discharge Survey, there were an estimated 897,000 discharges from short-stay hospitals in the United States with a first-listed, or principal, diagnosis of cerebrovascular disease (stroke). These patients, with a first-listed diagnosis of stroke, remained in the hospital for an average of 10.3 days. This means that over nine million days of patient care were required for those patients having a first-listed diagnosis of stroke. Approximately seven out of every ten patients (74 percent) with a first-listed diagnosis of stroke were at least 65 years of age; however, the proportions of men and women were about the same (53 percent women and 47 percent men). There were an additional 1.1 million stroke diagnoses (other than first-listed). Although some of these were additional diagnoses for the patients with a first-listed stroke diagnosis, the majority of these patients had some other type of diagnosis listed first on their medical record.

In 1983, the National Health Interview Survey collected data on the prevalence of cerebrovascular disease for the civilian noninstitutionalized population of the United States. The number of persons who reported ever having a stroke (and surviving) was 2,106,000 a rate of 9.2 per 1,000 persons. Of the age groups, those 65+ reported the highest rate, 51.1 per 1,000 persons. Males reported a higher rate of stroke than did females, 9.9 and 8.5 per 1,000 persons, respectively. These estimates only partially reflect the extent of this disease, however, since the fatality rates from it are high.

Information from the national vital statistics system indicates that cerebrovascular diseases were the third leading cause of death in the United States in 1983, accounting for about 156,000 deaths or 7.7 percent of all deaths in that year. Since 1950, the death rate from this cause has declined steadily. The risk of death from this cause is almost 20 percent higher for males than for females and about 80 percent higher for the black than for the white population.

The Sudden Infant Death Syndrome

Obligations

	1983	1984	1985	1986 Appropriation	1986 Available after sequestering	1986 Revised estimate	1987
National Institutes of Health:							
National Institute of Child Health and Human Development.......	$16,572,000	$17,184,000	$19,044,000	$19,600,000	$18,900,000	$18,800,000	$18,900,000
National Institute of Neurological & Communicative Disorders and Stroke.............	956,000	1,323,000	1,814,000	1,984,000	1,899,000	1,855,000	1,835,000
Total, NIH	17,528,000	18,507,000	20,858,000	21,584,000	20,799,000	20,655,000	20,735,000
TOTAL, PHS..........	17,528,000	18,507,000	20,858,000	21,584,000	20,799,000	20,655,000	20,735,000

NATIONAL INSTITUTES OF HEALTH

National Institute of Child Health and Human Development

SUDDEN INFANT DEATH SYNDROME (SIDS)

The Sudden Infant Death Syndrome (SIDS), also known as crib death, is defined as the sudden and unexpected death of any infant that cannot be explained by prior medical history or careful postmortem examination. A worldwide problem, SIDS remains the leading cause of death in American children ages 1 to 12 months. The estimated national incidence of SIDS is between 1.5 and 2.0 cases per 1,000 live births, which accounts for the loss of 5,000 to 6,000 infants annually. Most of these babies die quietly during what are considered normal sleep periods. Because there are no specific symptoms yet identifiable with SIDS, SIDS cannot be predicted and, therefore, cannot be prevented.

Many hypotheses have been advanced to explain SIDS, but the exact causes of this syndrome remain elusive. Scientists have ruled out choking, neglect, infection, and heredity as probable causes, and today believe that multiple factors rather than a single, common one are involved in SIDS.

The National Institute of Child Health and Human Development (NICHD) has the primary Federal responsibility for research on SIDS. Because of the suspected implication of the nervous system in SIDS, the National Institute of Neurological and Communicative Disorders and Stroke joined the NICHD in its quest to unravel the SIDS mystery.

The objectives of NICHD's SIDS program are to (1) identify characteristics of infants at risk of becoming SIDS victims, (2) understand the causes and mechanisms of sudden death, and (3) explore preventative approaches to the syndrome. NICHD's research emphasis has been both epidemiological and biomedical. The studies are sponsored by the Institute's Center for Research for Mothers and Children and the Epidemiology and Biometry Research Program.

EPIDEMIOLOGICAL RESEARCH

Study of Sudden Infant Death Syndrome Risk Factors in an effort to establish a profile of infants at risk for SIDS. Six medical centers across the United States participated in this retrospective study. Personal interviews were conducted with the mothers of more than 800 infants who had died of SIDS, and mothers of approximately 1,600 live infants born in the same months as the SIDS victims. Through these interviews, extensive data were gathered on the medical and personal histories of the infants and parents.

Information based on data from the first 400 SIDS cases and their matched controls was reported last year. During 1985, the complete data set was reviewed, and the final results of the survey were tabulated. The following profile of an infant at risk for SIDS, which emerged from the study's preliminary findings, was confirmed this year: In 90 percent of the SIDS cases, the infants were less than 6 months old; nearly 60 percent were boys; 24 percent weighed less than 5 1/2 pounds at birth; and 32 percent were born to teenage mothers. Black infants were found to be more than twice as likely as white babies to succumb to SIDS.

Also this year, a special analysis was targeted on the question of SIDS and DTP (diphtheria, tetanus, and pertussis) vaccination. Most children routinely receive a series of DTP inoculations beginning when they are 2 months old. Some recent reports have suggested a link between the DTP vaccine and SIDS. Based on an in-depth nationwide analysis of 716 SIDS cases, NICHD epidemiologists found that only 40 percent of the SIDS victims had received DTP shots. In control groups of living children matched in age, race and birth weight with the SIDS infants, the analysts found that 55 percent of the babies had received the DTP vaccine. Thus, this study provides strong evidence that there is no link between DTP vaccination and SIDS.

An NICHD-supported study is currently examining data collected in a British multicenter SIDS study. Tape recordings were made of 9,000 infants' cardiac and respiratory functions. The infants were then followed to see how many died of SIDS. By analyzing the tapes, it may be possible to determine if specific differences can be found between the SIDS victims and the survivors. If abnormalities can be detected in these infants--all of whom were less than 3 weeks old at the time the recordings were made--then the possibility of preventing SIDS could become a reality.

BIOMEDICAL RESEARCH

The NICHD's Center for Research for Mothers and Children supports the extramural research program on SIDS at the NICHD. This includes the collection of data on SIDS infants, and the support of research in animals whose early development and response mechanisms are similar to those in humans.

During 1985, NICHD-funded investigators continued to explore how early central nervous system development relates to the maturation of the circulatory, respiratory, and neurologic functions essential for an infant's adaptation to life outside the womb. Control of respiration by the central nervous system has been a particular area of intensive SIDS research. Because premature infants--a high risk group for SIDS--have frequent episodes of sleep apnea (periodic cessation of breathing during sleep), understanding the cause, effect, and consequences of abnormal breathing patterns in young infants may help to clarify the possible role of respiration in SIDS.

NICHD grantee Edward E. Lawson, at the University of North Carolina at Chapel Hill, used cats and piglets as models to study respiration in newborns. Dr. Lawson monitored the animals' responses to oxygen deficiency in order to understand what might occur in infants under similar conditions. Preliminary measurements, carried out with a novel and sophisticated technique, suggest that changes in the pH of the brain stem (the part of the brain that connects to the spinal cord) could be responsible for reduced rate and depth of breathing in newborns. This pH pattern was an unexpected finding, and is currently being examined further.

Studies by grantee Bradley T. Thach and his associates at Washington University in St. Louis, Missouri, investigated the effect of postfeeding regurgitation on the breathing patterns of infants with histories of prolonged apnea. Using rabbits as an experimental model, this research team showed that apnea may occur when stomach material reaches specific sites present in the body's upper airway passages and normal protective mechanisms--such as closure of the larynx and coordinated swallowing--are not functioning.

David M. Morens at the University of Hawaii has focused on a specific virus (dengue virus) as a useful model for studying how infants might defend themselves against a viral infection. In the tropics and subtropics, dengue virus causes an acute illness characterized by fever, joint and muscle pain, and headache. However, in Southeast Asia, children who had been infected by one strain of dengue develop, when infected by another strain of the virus, a more serious and often fatal hemorrhagic form of the disease.

Dengue shock syndrome in infants has a nearly identical age incidence curve to that of SIDS. While the two syndromes present different clinical pictures, an analogous mechanism to that thought to be operating in dengue may be postulated for SIDS with regard to common respiratory virus infection.

Under a Small Business Innovation Research Grant, James A. Walls of Biodyne, a company located in Orange, Connecticut, has developed a refined motion-sensitive apnea monitor which can detect apneic periods with greater sensitivity and consistency than previous alarm systems. The use of home apnea monitors for children at high risk for SIDS, and the possible role of home monitoring in the prevention of SIDS and its effect upon family life, will be the subject of a conference to be held at the NIH in September 1986.

NICHD intramural scientists currently are conducting a project that is closely connected to SIDS research. Dr. Joan L. Caddell, a guest researcher at NICHD, studied magnesium (Mg) deficiencies in premature newborns with underlying respiratory distress. Her retrospective review showed that infants given Mg supplements had no recurrence of apnea, while untreated babies suffered a significant number of recurrent apnea episodes that required hospital readmission. Dr. Caddell plans a prospective study of Mg supplementation in infants in the near future.

During the past year, Dr. Caddell also studied Mg deficiency syndrome in very young rats to try to clarify the role this substance plays in humans. She found that administration to normal rats of the same diuretic that is commonly given to babies with respiratory distress caused the animals to lose excessive amounts of Mg. Her research also showed that slight auditory stimuli provoked steep increases in adrenaline levels of Mg-deficient rats, but had no effect on adrenaline levels in Mg-fed animals. Such stimuli also caused seizures and death in Mg-deficient rats. At autopsy, the surfaces of the animals' lungs showed small hemorrhagic spots (petechiae)--an important common diagnostic finding in SIDS.

OUTLOOK FOR THE FUTURE

During the coming year, SIDS researchers will continue to explore the early development of the central nervous system. New techniques will be employed to further investigate tissue alterations in SIDS victims--particularly in the lungs and brain stem.

It is hoped that ongoing studies will improve our understanding of the processes that may be involved in SIDS, and help to uncover the causes of this disorder leading to the development of therapeutic and/or preventive interventions.

National Institute of Neurological and Communicative Disorders and Stroke

A contributing factor to Sudden Infant Death Syndrome (SIDS) may be abnormal functioning of the central nervous system. The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) supports a number of research grants on the basic mechanisms of central nervous system dysfunction, some of them related to SIDS.

NINCDS grantee Dr. Melissa M. Hines at the University of California at Los Angeles is examining how neurotransmitters can change the way hormones influence the developing central nervous system. This year she demonstrated in the rat fetus what may be the first instance of a neurotransmitter altering the hormone-related development of a neural structure. This discovery may help explain why the immature nervous system sometimes malfunctions, information that could be relevant to SIDS.

To understand how the neonatal brain can be damaged, NINCDS grantee Dr. Joseph F. Pasternak of the Evanston Hospital in Evanston, Illinois, is studying the effects of reduced oxygen and low blood pressure on brain blood flow and metabolism in puppies. This year Dr. Pasternak made the first quantitative measurements of brain glucose metabolism in puppies younger than 72 hours, the age at which puppies are most likely to suffer a brain hemorrhage. He and his colleagues have also found preliminary evidence that oxygen-starved blood causes greater metabolic damage to the hemispheres of the brain than to the brain stem. Dr. Pasternak's group is measuring brain blood flow in puppies and examining structural differences in brain blood vessels that could make certain brain areas more vulnerable than others to injury.

These basic studies are providing fundamental information about nervous system function, and are building the basis for improved understanding of the neurological processes that may be involved in SIDS.

HEALTH RESOURCE AND SERVICE ADMINISTRATION
Bureau of Health Care Delivery and Assistance

SUDDEN INFANT DEATH SYNDROME PROGRAM

Activities relating to Sudden Infant Death Syndrome (SIDS) were formerly authorized under Title XI of the Public Health Service Act. These activities included: (a) counseling and information services for families whose infants died suddenly and unexpectedly; (b) developing and disseminating information and educational materials relating to SIDS for health care and related personnel including volunteers and the general public; and (c) the collection, analysis and dissemination of SIDS statistical data and information.

The major purposes of the program are: (a) to assist families and prevent secondary trauma by providing informed, humane, coordinated and comprehensive information and counseling services during the periods of bereavement and grief; (b) to keep health care and related personnel, volunteers, and the public, who may encounter these families, informed about SIDS and its effect upon the family survivors, and about their responsibilities to families faced with this crisis; (c) to apply research findings in a timely and orderly manner in order to identify and diagnose infants at risk for SIDS so they can receive therapeutic intervention; and ultimately, (d) to prevent these tragic deaths.

The strategy for State implementation of the first goal is to maximize the resources by establishing comprehensive and coordinated State systems for immediate and ongoing services utilizing existing county, State and Federal facilities. Cooperative working relationships with appropriate resources within a State or a defined smaller geographic area can provide prompt case identification, confirmation of the cause of death, prompt notification of the family about the cause of death, as well as early and periodic counseling services for family survivors. The number of infant death investigations, including autopsies and the use of SIDS on death certificates is increasing annually. Coordination of emergency medical and safety service providers, public health and mental health services, and volunteers make it possible for concerned individuals to have access to SIDS information, appropriate notification about their infant's cause of death, and referral to appropriate resources for counseling and/or peer support when indicated.

Implementation of the second objective for development and dissemination of information and educational materials is conducted at both the national and project levels. The Division of Maternal and Child Health (DMCH) has developed and produced major printed and audiovisual materials in a variety of formats to meet the needs of both the professional and the general public. These materials are distributed through the National SIDS Clearinghouse which is supported by DMCH. The Clearinghouse also maintains a current database of SIDS and related information; develops "Fact Sheets" on selected topics; and produces resource directories. Perhaps more importantly, the "Information Exchange", a quarterly newsletter is published and distributed. This provides a national mechanism for reciprocal communication with a wide variety organizations, agencies, researchers, practioners and volunteers concerned about SIDS and its effects on families.

DMCH also supports applied reseach grants related to SIDS. One such example is a three year project to study the behavorial responses of parents to SIDS deaths and those of parents whose infants die of other causes.

A study of SIDS programs conducted by the States was recently completed. The specific findings will be made available early in 1985. Over all indications are that every State but one provides some degree of services, public information and professional education appropriate for a SIDS program but the level of effort has generally decreased under the Block Grant Program.

Because the association of prolonged infantile apenea with SIDS continues to present concerns for clinical practitioners, a series of workshops were supported by DMCH as a means of providing consultation. A monograph on the clinical management of the infant as increased risk for SIDS will be forth coming in 1985. It will be made available to physicians and others concerned with this subset of infants at high risk for SIDS. The Division also assists in planning and conducting SIDS programs at national meetings of professional organizations and other Federal agencies. Informed staff continue to respond to frequent requests for technical assistance and consultation from individual, agencies and organizations both public and private.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

SUDDEN INFANT DEATH SYNDROME

In the United States in 1983, Sudden Infant Death Syndrome (SIDS), also known as crib death, was the second leading cause of infant death. It accounted for about 5,300 deaths to children under 1 year of age, that is, a rate of 1.5 per 1,000 live births. Most victims are between the ages of 1 to 3 months.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
National Institutes of Health

National Institute of Environmental Health Sciences

Plan for Studying the Human Health Effects of Acid Rain

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Plan for Studying the Human Health Effects of Acid Rain

Executive Summary

In House Report No. 99-289, the Committee on Appropriations requested that the National Institute of Environmental Health Sciences (NIEHS) develop a comprehensive plan for studying the human health effects of acid rain and that the plan include a detailed outline of the Institute's programmatic, staffing, research and funding requirements to address this problem. The following is submitted in response to that request.

In response to previous requests of the Committee, the Institute held a workshop (December 1983) and an international conference (November 1984) to determine research needed to address the human health aspects of the acid rain problem.

Research needs involve two broad areas of health concern, respiratory diseases related to inhalation of acid pollutants and potential effects of increased human exposure to toxic metals.

The NIEHS presently supports a wide range of research activities that reflect these previously determined research needs. In addition, new studies were begun in the past year regarding the identification of specific components of acid rain which are primarily responsible for lung damage.

New research initiatives will involve new epidemiologic studies, research on synergisms and antagonisms between toxic components of acid rain, and studies on the potential health effects of aluminum.

A workshop for review of the research plan will be held in 1986. An international conference is planned during the next two years.

The new initiatives are estimated to cost about three million dollars and require two positions to manage.

Plan for Studying the Human Health Effects of Acid Rain

INTRODUCTION

In its report on the Fiscal Year 1986 budget for the Department of Health and Human Services, the Committee on Appropriations stated:

> The Committee understands that a small amount of the funds added to the health science centers program in fiscal year 1985 may be used to begin to expand and initiate original research on the health effects of acid rain on humans, as the Committee requested in last year's report. The Committee is concerned with addressing this problem and therefore requests the Institute to develop a comprehensive plan for studying the human health effects of acid rain. This plan should be submitted to the Committee prior to hearings on the fiscal year 1987 budget, and should include a detailed outline of the Institute's programmatic, staffing, research and funding requirements to properly address this problem of growing national and international concern. (House Report No. 99-289, p. 70)

The following report has been prepared by the National Institutes of Health of the Department of Health and Human Services in response to this request.

BACKGROUND

In the House Appropriations report 98-357 (September 1983), the National Institute of Environmental Health Sciences (NIEHS) was asked to convene a workshop of scientists in collaboration with the Environmental Protection Agency (EPA) to assess the state of knowledge on the possible impact of acid rain on human health. In response to that request, a group of scientists was convened at the NIEHS on December 9, 1983, for a workshop and a report was subsequently submitted to the Committee in January 1984. This report has recently been published (Environmental Health Perspectives 60: 355-368, 1985) (Appendix 1). The following statement is the summary from the report:

> This report summarizes the potential impact of the acid precipitation phenomenon on human health. There are two major components to this phenomenon: the predepositional phase, during which there is direct human exposure to acidic substances from ambient air, and the post-depositional phase, in which the deposition of acid materials on water and soil results in the mobilization, transport, and even chemical transformation of toxic metals. Acidification increases bioconversion of mercury to methylmercury, which accumulates in fish, increasing the risk to toxicity in people who eat fish. Increase in water and soil content of lead and cadmium increases human exposure to these metals which become additive to other sources presently under regulatory control. The potential adverse health effects of increased human exposure to aluminum is not known at the present time.

An important concept that was emphasized in the report was that acid rain is a phenomenon--not a toxic substance per se--but it can be the reason for increased human exposure to air pollutants and toxic metals. Therefore, research which addresses the human health effects of the acid rain phenomenon is not separable from investigations of the specific toxic substance involved. The acid rain phenomenon contributes to human exposure to these substances so that any consideration of the impact of the acid rain phenomenon on human health must involve a wide range of academic disciplines.

As a follow-up to the workshop, the NIEHS in collaboration with the U.S. Environmental Protection Agency (EPA) convened an international conference of scientists at NIEHS on November 15-16, 1984, to discuss the potential human health effects of acid rain. Twenty-four scientists from four countries, most of whom have conducted considerable prior research on this problem participated in the conference (see Appendix 2 for agenda). The major ojectives of the conference were to identify the body of information that pertains to the possible health effects of acid rain and to identify research needs. The papers presented at the conference were published in Environmental Health Perspectives, vol. 63, November 1985.

Research needs were addressed in terms of two major components of the acid rain issue affecting human health: (1) direct effects of acid rain on human health, particularly respiratory effects related to inhalation of acid pollutants; and, (2) indirect effects of acid rain on human health, including potential health effects of increased human exposure to toxic metals.

In addition, the report of the EPA National Acid Precipitation Program ("The Acidic Deposition Phenomenon and its Effects, Critical Assessment Review Papers," Volume II, EPA, 1983), and the report of the National Research Council on Acid Deposition, "Atmospheric Processes in Eastern North America" (1983) were consulted. Possible health effects that have been considered by others are effects on skin and eyes but, at the present time at least, there is not sufficient evidence to warrant specific attention to these topics.

DISCUSSION

The following research plan was developed as a result of discussion by the scientific staff of the NIEHS and consideration of the workshop report and of recommendations of the November 1984 NIEHS conference.

Research Needs

The primary cause of acid deposition is generally understood to be the oxidation of sulfur, nitrogen, and carbon compounds emitted to the atmosphere from natural and man-made sources. These pollutants may be removed directly from the atmosphere as dry or wet acidic deposition or may first undergo atmospheric transformations to sulfuric acid, nitric acid, and several chemical forms of particulate substances. Photochemical oxidants, such as ozone and hydrogen peroxide, and reactive volatile organic compounds known to play a role in the transformations, are also present in relatively high levels in the same geographic regions as the pollutants.

Thus, the atmospheric precursors to acid deposition involve most of the "traditional" air pollutants; namely, sulfur oxides, nitrogen oxides, particulate matter, and photochemical oxidants. Deleterious health effects have been attributed to inhalation of high concentrations of these pollutants, and numerous literature reviews and documents have been prepared on their known and potential health effects (see Appendix 1). However, it has been concluded that there is need to better establish the contribution of acid deposition to human exposure to these pollutants and the potential health effects resulting from inhaling several specific acid sulfate and nitrate components that are present in elevated concentrations in geographical regions where acid deposition is greatest. There is need for epidemiologic studies on low level sulfuric acid exposures as occur in minor periodic environmental pollution episodes (12-30 of these transient episodes occur in limited portions of eastern United States per year). And, finally, additional studies are needed to determine the minimal toxic levels of acidic pollutants (sulfuric and nitric acids, and sulfate and nitrate compounds, hydrogen ion) that produce respiratory effects in susceptible populations, such as asthmatics, people with chronic bronchitis, emphysema, etc.

Although much is known about the biologic effects of lead, cadmium, and mercury, there are large gaps in knowledge about the contribution of acidic deposition to the ecological transport (in soil, water, and living things) that results in increased human exposure to lead, cadmium, and mercury. For each of these metals, it becomes increasingly important to know the minimal levels of human exposure that produce an undesirable health effect, the factors that affect human susceptibility, and safe, effective methods for removal of excess metals from people (chelation therapy).

There is particular need for research on the influence of acid rain on the biology and possible health effects of exposure to aluminum compounds including the influence of acidity of water on speciation (chemical form of aluminum), and solubility and concentration in water. In recent years, it has been noted that an encephalopathy (brain injury) occurs in hemodialysis patients that is related to aluminum content of water, and that aluminum is present in neural tangles in the central nervous system of persons with Alzheimer disease. There are gaps in the understanding of the extent to which aluminum may play a role in the causation of the hemodialysis encephalopathy and in Alzheimer disease. There is need to identify the role of acid rain in the chemical form and transport of aluminum in human tissues, particularly across the blood-brain barrier as well as the cellular pathology of aluminum.

NIEHS-Supported Ongoing Research Activities

Through its research grants, the NIEHS presently supports a large body of research on human health effects of acidic pollutants and toxic metals in which human exposure is increased because of the acid rain phenomenon. These activities, including major recent accomplishments and research plans, are highlighted in Appendix 3.

New NIEHS-Supported Studies

Two NIEHS Environmental Health Sciences Centers have initiated additional studies with funds made available in Fiscal Year 1985. These studies are intended to identify specific components of acid rain which are primarily responsible for lung damage.

A project to be carried out at the University of Rochester will compare effects of sulfuric acid and more neutral sulfate compounds (ammonium sulfate) present in acid rain on human lungs. These studies will be conducted on human volunteers exposed to controlled levels in specifically designed exposure chambers. The objective is to determine whether lung damage due to sulfate components of acid rain is due to acidity per se or the sulfate in the compound.

The project to be carried out at the New York University is a laboratory study aimed at correlating pulmonary structural damage with deficits in lung defense mechanisms that result from acute and chronic exposure to acid sulfate and other gaseous pollutants in acid rain.

Plans for New Initiatives, Fiscal Year 1986

Review of NIEHS-supported ongoing studies (see Appendix 3) in the context of research needs that were identified in the NIEHS Conference on

Potential Health Effects of Acid Rain (November 1984) indicates that the present program supports a broad range of research activities recommended by scientists at the NIEHS workshop (1983) and conference (1984). These recommendations are detailed in the workshop report (Appendix 1) and the summary papers of the conference in Environmental Health Perspectives, November 1985.

Three additional needs are as follows: the first involves more and better epidemiological studies that relate clinical effects of exposure to episodes of acid rain. Approaches to this problem may include the correlation of excesses in hospital admissions with indices of acid rain, and levels of ambient sulfate, and ozone.

A second need concerns better understanding between synergisms or antagonisms among toxic substances involved in the acid rain phenomenon. In terms of gaseous air pollutants, specific roles of components of acidic aerosols (hydrogen ion, sulfuric acid, ammonium sulfate, and other inorganic sulfate compounds) are receiving only limited study. An essential part of this need is development of a methodology that will discern each component within the ambient environment. Synergisms and antagonism between potentially toxic metals and metabolism of essential metals are also of importance in the understanding of minimally toxic effects.

The third need concerns potential health effects of aluminum. Basic and clinical information is needed regarding effects of acidification of water on aluminum absorption, and deposition in mammalian system, and possible relationship of aluminum accumulation in body tissues to specific diseases, e.g., diseases of kidney, bone, and nervous system.

Plan for Follow-up Workshops/Conferences

Workshops or conferences will be held as a means to assure that the plan is being implemented and to initiate new research needs. A workshop is planned for late 1986.

An international conference to serve as follow-up to the international conference held at NIEHS in November 1984 will be held in 1987 or 1988.

CONCLUSIONS AND RECOMMENDATIONS

The NIEHS supports a broadly designed program that addresses the potential human health effects of the acid rain phenomenon (Appendix 3). This research is responsive to needs identified in an NIEHS-supported workshop and conference. However, there are specific areas where new research could be directed and/or expanded.

In response to recommendations of the House Committee on Appropriations, two new projects were started in 1985 directed to a specific and important gap in present knowledge: the identification of individual gaseous components of acid rain that are primarily responsible for lung damage.

Review of the current NIEHS program to study the health effects of acid rain suggests that present activities need to be continued and, in some instances, expanded. Some of these activities are longitudinal in design (Harvard Six Cities Study, description on first page of Appendix 3) and the major results of the study will occur in the future. In addition, areas of research need or gaps in the present program have been identified and plans are underway to address these needs.

Funding Requirements for New Acid Rain Initiatives

The new initiatives will be instituted by issuing Requests for Applications (RFAs). The number of new proposals resulting from RFAs that can be supported will be related to availability of funds. It is estimated that approximately three million dollars will support the peer reviewed and scientifically approved research proposals addressing the three new research initiatives: epidemiologic studies, studies identifying synergisms or antagonisms among toxic substances involved in the acid rain phenomenon, and research activities regarding aluminum toxicity. This estimate is based on the current cost of research as it relates to epidemiologic studies and laboratory research projects.

Staffing Requirements for New Acid Rain Initiatives

Because the proposed new activities will be conducted through the NIEHS extramural program, actual performance of research will be done at universities and research institutes. Two positions are required to manage an activity of this size.

Appendix 1

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Potential Human Health Effects of Acid Rain: Report of a Workshop.

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This report summarizes the potential impact of the acid precipitation phenomenon on human health. There are two major components to this phenomenon: the predepositional phase, during which there is direct human exposure to acidic substances from ambient air, and the post-depositional phase, in which the deposition of acid materials on water and soil results in the mobilization, transport, and even chemical transformation of toxic metals. Acidification increases bioconversion of mercury to methylmercury, which accumulates in fish, increasing the risk to toxicity in people who eat fish. Increase in water and soil content of lead and cadmium increases human exposure to these metals which become additive to other sources presently under regulatory control. The potential adverse health effects of increased human exposure to aluminum is not known at the present time.

Introduction

This report results from a request by the Committee on Appropriations of the U.S. House of Representatives that the National Institute of Environmental Health Sciences (NIEHS) convene a workshop of scientists with an interest in the area of research on possible health effects associated with acid rain exposure. The workshop was convened by the NIEHS on December 9, 1983, and was attended by both government and nongovernment scientists with expertise in various topics related to the potential health effects of the acid rain phenomenon. The resultant report is largely a review of the current information available on this topic. Specific conclusions are cited at the end of the report.

As background for these considerations, it was determined that the acid rain phenomenon has two components: the predeposition phase, which involves air pollutants, and a postdeposition phase concerning the effects of deposition of acidic substances in water or dry surfaces, including soils and buildings. The effects of the predeposition phase are sometimes referred to as direct or primary, whereas postdeposition effects are not likely to appear immediately and may be regarded as secondary or indirect. This discussion considers the immediate as well as long-term potential impact on human health from both phases of the acid rain phenomenon.

Air Pollution Precursors or Substances Contained in Acid Rain Before Deposition

The primary cause of acid deposition is generally understood to be the oxidation of sulfur, nitrogen, and carbon compounds emitted to the atmosphere from natural and man-made sources. On a global scale, natural sources (e.g., swamps, marshes, lightning) are significant, but in eastern North America an estimated 90 to 95% of precipitation acidity is thought to be related to human activities, largely the combustion of fossil fuels (e.g., power plants, industrial sources, home heating, motor vehicles) and smelting of sulfur containing ores (*1*).

The region of highest acid deposition in North America corresponds closely to the region of heavy industrialization and urbanization along the Ohio River Valley and eastern seaboard, where both anthropogenic emissions and atmospheric loadings of sulfur and nitrogen oxides are also high. These pollutants may be removed directly from the atmosphere as dry or wet acidic deposition or may first undergo atmospheric transformations to sulfuric acid, nitric acid, and several particulate species

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Photochemical oxidants, such as ozone and hydrogen peroxide, and reactive volatile organic compounds known to play a role in the transformations, are also present in relatively high levels in the same industrialized and urbanized regions.

Thus, the atmospheric precursors to acid deposition involve most of the "traditional" air pollutants; namely, sulfur dioxide, nitrogen oxides, particulate matter, and photochemical oxidants. Deleterious effects have long been attributed to inhalation of high concentrations of these pollutants, and numerous literature reviews and documents have been prepared on their known and potential health effects *(2–9)*. The workshop reviewed the contribution of acid deposition to human exposure to these pollutants and the potential health effects of inhaling several specific acid sulfate and nitrate components that are present in elevated concentrations in geographical regions where acid deposition is greatest.

Atmospheric sulfates are derived principally from atmospheric transformations of gaseous sulfur dioxide. The major sulfate species occur as fine (< 2.5 µm in size) droplets or solid particles that include various mixtures of hydrogen and ammonium ions ranging in acidity from sulfuric acid to neutral ammonium sulfate. Elevated levels of sulfates occur on a regional scale throughout eastern North America and are highest in the Ohio River Valley. Multi-day events of elevated sulfate concentrations accompanied by high photochemical oxidant levels occur over large-scale regions during the summer months. Elevated sulfate events can also happen in other seasons. Although speciation data are very limited, during such events sulfuric acid equivalent levels may reach 15 to 20 μg^3 or more *(10)*.

The more acidic transformation product of nitrogen oxides is nitric acid which at typical ambient humidity and temperature is present as a vapor. Based on limited measurements, ambient concentrations are generally very low, but levels as high as 10 to 20 μg^3 have been observed in the Ohio River Valley *(11)*. Particulate nitrate levels (e.g., ammonium nitrate) appear to be low in eastern North America. The highest levels of both nitric acid and nitrate particles occur in western urban areas such as Los Angeles. In southern California, acid fogs have been reported in which nitric acid appears to dominate droplet acidity *(12)*.

Nature of Toxic Materials Released Following Deposition

Once deposited, atmospheric acids and acid forming sulfur and nitrogen containing species do not of themselves appear to present a health threat. They may, however, indirectly mobilize toxic materials and add to total human exposure to these materials. To date, the major areas of potential concern include contamination of edible fish by toxic metals, principally mercury, soil leaching in acidified watersheds and corrosion of water and storage distribution systems, leading to elevated levels of toxic elements, chiefly lead, cadmium, and aluminum.

In general, the geographic areas in which such increased exposures might occur are limited to the same regions that appear sensitive to long-term acidification of aquatic ecosystems. This includes large portions of the Northeast, portions of the Appalachian mountains and some of the upper Midwest. Areas that have usual accumulations of metals in sediments or soils and areas which lack drinking water treatment facilities may also be sensitive.

Health Effects of Air Pollutant Precursors to Acid Deposition

General Comments

The health effects of the major pre-deposition pollutants of acid rain, sulfur and nitrogen oxides, have been extensively reviewed by the National Academy of Sciences *(2–4)* and the Environmental Protection Agency *(6,7)*. These reports conclude that atmospheric oxides of sulfur and nitrogen can cause human health effects. This report summarizes pertinent information in those documents and describes some of the more recently available data.

Knowledge of the effects of sulfur and nitrogen oxides is derived from three major types of studies —epidemiology, human clinical, and animal toxicology. Epidemiological evidence provides direct information on the responses of humans to actually encountered pollutant conditions, typically consisting of low levels of pollutant mixtures. Both acute and chronic effects can be studied. However, the complexities of human activities result in confounding factors that are not present in chamber studies with man or animals. Human clinical studies involve controlled short-term exposures of volunteers to single or, in a few cases, multiple pollutants. Data can be interpreted directly to human health risk. However, such studies are not designed to cause irreversible effects and, thus, they are very limited. With respect to animal studies, on the other hand, acute and chronic studies are possible, and effects on tissues such as the lung can be studied. Nonetheless, concentrations causing effects in animals cannot yet be directly quantitatively extrapolated to man. Therefore, optimal understanding of the health effects of these pollutants requires integrating information from all three experimental approaches.

Sulfur Oxides

Human Epidemiologic Evidence. There is little information that directly links acid precipitation with effects on human beings. Much of this has been due to the difficulties in measuring the components in the atmosphere. Frequently, the measurement has been of the water-soluble sulfates without specification as to the type of sulfate present. Evidence from animal studies and limited studies on human beings in chambers do indicate that sulfuric acid for the equivalent amounts of sulfur and of sulfur particle size is more reactive biologically than ammonium sulfate or sodium sulfate. Thus it appears that it is the acidity or the hydrogen ion concentration rather than the sulfate that is the active component. There is a need to develop better methods to analyze air samples for sulfuric acid or nitric acid. Collection requires that the sample be protected from ammonia contamination which would result in measuring lower concentrations of sulfuric acid than was originally present.

There is a certain amount of data, however, that can be used to demonstrate that acid particulate matter may have an effect on human health. The episodes of high pollution in London (*13*), the Meuse Valley (*14*), and Donora, Pennsylvania (*15*), undoubtedly had high acid content in their pollution mix. The concentrations were measured during some of the London episodes (*16,17*); Hemion (*18*) estimated sulfate concentration in the Donora episode. Presumably, similar results would have been obtained in the other event. The persons most effected were the elderly, especially those with cardiovascular diseases, and young children. The concentrations associated with these episodes were high —probably in the range of milligrams per cubic meter. It was not clear which component of this pollution mix was the active agent or whether they worked in conjunction. One hypothesis held that the sulfur dioxide was absorbed into the particles and was then converted to sulfuric acid by the time it was delivered to the lung. Another held that the sulfuric acid could be directly absorbed onto the particles or formed their own aqueous droplet. In addition there may have been synergism between the soot particles and the sulfuric acid droplet.

More recent studies (*19,20*) have used sulfate as a surrogate for sulfuric acid and have presented results that suggest there may be an effect. As with virtually all of these studies, there has been considerable confounding of the effects of one pollutant with other pollutants and it has been virtually impossible to isolate which component was the active one or whether they were acting in concordance.

The Community Health and Environmental Surveillance System (CHESS) studies (*20*), although severely criticized, did draw more attention to the possible effects of acid sulfates. Earlier, Waller and Lawther (*21*) had suggested that sulfuric acid was an active ingredient in the London fogs.

Thus, there is suggestive evidence that sulfates or, more specifically, acidic sulfates can have an effect on health. The evidence from epidemiologic studies is weak due to the confounding factors. Better information as to the effect of sulfuric acid comes from human and animal exposure studies.

In at least one of the on-going Harvard Six Cities epidemiologic studies, efforts are being made to measure sulfuric acid and ammonium sulfates. Thus far only a couple of cities have been monitored. The others will be included later after the initial field testing of the instruments has proven to be satisfactory.

Controlled Chamber Studies with Humans and Experimental Animals. Standard tests of lung mechanics have been used most often as criteria of irritancy potential due to inhaled sulfur oxide aerosols. However, attempts to produce significant changes in respiratory function of resting healthy humans and experimental animals, with the possible exception of the guinea pig, with submicrometer aerosols at concentrations of up to 1 mg/m^3 for up to 1 hr were largely unsuccessful (*22–27*). With exercise, a slight depression in some indices was noted after a 2-hr exposure to 1 mg/m^3 sulfuric acid (*28*). Using bronchial provocation testing following acid sulfate exposures for 16 min at 1 mg/m^3, Utell et al. (*29*) showed a potentiation of human response to carbachol challenge in relation to aerosol acidity, i.e., sulfuric acid > ammonium bisulfate > sodium bisulfate > ammonium sulfate. A few studies have examined responses in people with extrinsic asthma; results are contradictory. Avol et al. (*30*) noted minor changes in pulmonary resistance in two of six asthmatics exposed to 0.075 mg/m^3 (0.3 μm) sulfuric acid for 2 hr. Sackner and Ford (*31*) found no changes in lung mechanics in adult asthmatics exposed to sulfuric acid at 1 mg/m^3 (1.5 μm) for 10 min, while Spektor (*32*) found changes in some indices due to 1-hr exposures to a submicrometer aerosol at the same concentration, and Utell et al. (*29*) noted changes in specific airway conductance after exposure to sulfuric acid at 0.45 or 1 mg/m^3 for 16 min. Most recently, Koenig et al. (*33*) noted significant alteration in lung mechanics of adolescent asthmatics after exposure for 30 min at rest plus 10 min with exercise to 0.1 mg/m^3 sulfuric acid.

Another aspect of lung physiology which has been examined is clearance function, which is involved in lung defense. Decreased ciliary beat frequency was observed in tracheal explants obtained from hamsters exposed for 2–3 hr to submicrometer amounts of sulfuric acid (0.88–1.1 mg/m^3) (*34,35*). Effects upon tracheobronchial mucociliary clearance function in intact animals, which is a more sensitive index than mechanical function, have been reviewed recently by Schlesinger (*36*). Transient clearance rate alterations have been noted in humans and experimental animals following 1-hr exposures to submicrometer amounts of sulfuric acid at 0.095–0.1 mg/m^3 (*25,36,37*). Levels of 1.7 mg/m^3 ammonium sulfate were required for similar responses (*36*) in experimental animals, and no changes have been found for ammonium sulfate at 3–3.6 mg/m^3 for 1–4 hr (*38*).

Transient changes may become long-lasting. Schlesinger et al. (*27*) demonstrated persistently slowed clearance in two of four experimental animals (donkeys) after six individual 1-hr exposures to sulfuric acid at 0.2–1.0 mg/m^3. Subsequently, four animals were exposed 1 hr daily, 5 days/week to sulfuric acid at $\sim$ 0.1 mg/m^3. Within the first few weeks of exposure, all four developed erratic clearance rates, while two developed persistently slowed bronchial clearance during the second three months of exposure and during four months of follow-up measurements.

Because persistent clearance alteration is seen in chronic bronchitis, sulfuric acid has been hypothesized as having a role in pathogenesis of bronchitis. Although direct evidence for an association between sulfuric acid and chronic bronchitis is lacking, this hypothesis is strengthened by comparing studies with submicrometer amounts of sulfuric acid and whole fresh cigarette smoke exposures with donkeys and humans (*40*); cigarettes are involved in the etiology of human chronic bronchitis. The effects of both agents on mucociliary clearance are essentially the same in terms of transient acceleration of clearance in low dose exposures, transient slowing following high doses, and alteration in clearance rate persisting for several months following multiple exposures. A recent study by Schlesinger et al. (*41*) adds further support. Rabbits exposed to sulfuric acid at $\sim$0.25–0.5 mg/m for 1 hr/day, 5 days/week, for four weeks demonstrated an increase in secretory cells in the epithelium of small airways, a hallmark of chronic bronchitis. In addition, in some cases, the epithelium was thickened and airway diameters were narrowed.

Clearance from the respiratory airways is mediated by alveolar macrophages, which are also responsible for the lung's bacteriocidal function. Few data exist on effects in this region; and available studies use unrealistically high levels of acid sulfates. Mice exposed to small amounts 80, 150 or 300 mg/m^3 of sulfuric acid for 3 hr showed enhanced mortality due to a subsequently inhaled bacterial aerosol only at the highest concentration, and this was probably due to tissue damage (*42*); no change was noted in the numbers of macrophages in lavage fluid. Macrophages harvested from mice exposed to sulfuric acid from 125 to 154 mg/m^3 from 10–14 days showed decreased interferon titers in their culture fluid (*43*). In the only study of effects upon alveolar clearance in intact animals (*38*), rats exposed for 4 hr (at 39% R.H.) to 3.6 mg/m^3 sulfuric acid exhibited clearance deceleration 2–17 days after exposure, a phase mediated by macrophages.

There are few investigations of the chronic effects of sulfates and these have only been reported with sulfuric acid. Most were conducted at a time before highly sensitive quantitative measurement techniques for lung morphology were available. Interpretation of the studies is made difficult because whole body exposures were used, thereby permitting an uncontrolled neutralization of sulfuric acid within the chamber atmosphere. Therefore, sulfuric acid concentration-response effects cannot be determined with precision.

Guinea pigs were unaffected by a one-year exposure of up to 0.9 mg/m^3 sulfuric acid (*44,45*). Monkeys experienced a transient alteration in pulmonary function during a one and one-half year exposure to submicrometer, but not larger, sulfuric acid at 0.4–0.5 mg/m^3 (*44*). Lung structure was also changed by some of the sulfuric acid concentrations; a typical finding was thickening of the walls of respiratory bronchioles. However, the responses were not consistently relatable to concentration or particle size of sulfuric acid. Lung structure of dogs was not affected by about one and one-half years of exposure to 0.9 mg/m^3 sulfuric acid, although there were some changes in pulmonary function (*46,47*).

Chronic effects of ammonium sulfate are unknown. Recent subchronic studies (exposures of 5 days/week for 4 weeks) have shown that ammonium sulfate is not as innocuous as presumed from acute exposure studies (*48*). A level of 1 mg/m^3 ammonium sulfate caused structural and functional changes in the lungs of rats, and to a lesser degree in guinea pigs. Those animals with laboratory-induced emphysema appeared to be more resistant.

The interaction of sulfuric acid with other particles has been the subject of several studies. Sulfuric acid did not potentiate the effects of ozone, nitrogen dioxide, or sulfur dioxide in normal human subjects exposed acutely (*49*). Guinea pigs exposed to various combinations of sulfuric acid, sulfur dioxide, and fly ash for one year experienced no changes in pulmonary function or structure (*45*). Monkeys exposed for one and one-half years to similar combinations having about 0.9 mg/m^3 sulfuric acid had no alterations in pulmonary function. However, lung structure was altered. Fly ash did not enhance the effects of sulfuric acid.

The most extensive interaction study was conducted with dogs exposed for about five and one-half years to 1.1 mg/m^3 sulfur dioxide plus 0.09 mg/m^3 sulfuric acid and then allowed to remain in unpolluted air for about two and one-half years (*50*). Periodic examinations were made, and some changes in pulmonary functions were noted throughout exposure. The functional losses continued following the termination of exposure. Morphometric measurements of the lungs were made at the two and one-half year post-exposure period (*51*). Several types of changes were observed. The most noteworthy were changes that the authors considered analogous to an incipient stage of human centrolobular emphysema.

The only significant body of data for the interaction of sulfuric acid with gases involves ozone. Generally, the results of these studies are dependent upon the biological system examined and the exposure regimen utilized. Last and Cross (*52*) found synergistic effects of 1 mg/m^3 sulfuric acid and 0.4–0.5 ppm ozone on glycoprotein synthesis (an index of mucus production) in rats. Antagonistic effects on ciliary beating frequency were observed when hamsters were exposed in sequence, first to 0.1 ppm ozone and then to 0.9 mg/m^3 sulfuric acid ([illegible]). Gardner et al. (*53*) showed additive effects of 0.9 mg/m^3 sulfuric acid and 0.1 ppm ozone for susceptibility to bacterial lung infections of mice exposed in sequence to ozone first.

Nitrogen Oxides

There are virtually no epidemiologic, human clinical, or animal toxicological studies that have examined the effects of nitric acid. Very few data exist concerning response to inhaled particulate nitrogen oxides; those that are available relate most solely to pulmonary mechanics. Dogs exposed to sodium nitrate at 10 mg/m (0.1 μm) for 7.5 min or sheep exposed to 5 mg/m for 4 hr showed no significant change in lung mechanical function (*54*). Similar negative results were obtained in healthy human subjects exposed to sodium nitrate at 1 mg/m for 10 min (*54*) or in healthy and asthmatic adults exposed for 2 hr (with intermittent exercise) to ammonium nitrate at 0.2 mg/m (1.1 μm) (*55*). In a study by Utell et al. (*29*), no significant enhanced effect of a carbachol (bronchoconstrictor) challenge was observed in either a group of normals or asthmatics previously exposed to sodium nitrate at 7 mg/m (0.46 μm) for 16 min; however, two asthmatics did show mild potentiation of the carbachol-induced bronchoconstriction after sodium nitrate exposure. Normal and allergic sheep exposed for 4 hr to 1.6 ppm nitric acid vapor showed no change in pulmonary flow resistance (*56*). With bronchial provocation testing, no significant change in airway reactivity was noted in the normal animals, but mild hyperactivity occurred in allergic sheep within 24 hr after exposure.

Stutts et al. (*57*) found that ammonium nitrate could alter sodium and chloride transport across canine tracheal epithelium. However, the response was ascribed to ammonium ion rather than nitrate ion since sodium nitrate had no effect.

Health Effects That May Occur During the Postdepositional Stage of Acid Rain

General Comments

Several steps are involved in the postdepositional stage of acid rain, so that the potential effects on health resulting from changes occurring during this stage are sometimes referred to as indirect effects. The steps in the postdepositional stage include mobilization of metals from generally fixed sites, such as ores and insoluble deposits, to media that contribute to human exposure, such as water and food, and transformation to more toxic forms (alkylation of mercury to methylmercury). Considerable attention and research have focused on the ecological changes that are involved in the acidic postdeposition stage, including effects on soil systems, vegetation, aquatic chemistry and aquatic biology, particularly the impact on reproduction and growth of fish. These effects are well documented in other major studies, such as the Report of the National Academy of Sciences on Acid Rain Deposition (*1*). It may be argued that effects on soil that influence the ability to grow food crops, effects on crops themselves, and reduction in consumable fish are, in themselves, indirect threats to human health. However, the level of such effects is not sufficient to support such an argument. In fact, no effects on human health have been demonstrated to date to be the result of the sequence of changes that occur during the postdepositional stage of the acid rain phenomenon. The lack of documented effects may reflect that no such effects exist or that interest in the phenomenon of acid rain is recent; few, if any, investigations of possible linkages have been made. In principle, acid rain in the postdeposition stage may influence human exposure to toxic chemicals by two main routes: the accumulation of chemicals in food chains and the contamination of drinking water. Metals are the substances primarily affected, particularly lead, cadmium, mercury, and aluminum.

Mobilization of Metals during the Postdeposition Stage

Williams (*58*) had pointed out that metal ion interactions in biology can be divided into three classes: metal ions in fast exchange; metal ions in intermediary exchange; and metal ions in slow exchange. These changes occur with organic ligands to which metal ions can coordinate. Metal ions in fast exchange are especially important in toxicity considerations. Examples of elements in fast exchange in biology are the alkali metals, sodium and potassium, and the alkali earth metals, calcium and magnesium, as well as the most important hydrogen ion. Solid-state ions of the elements lead, cadmium, and aluminum can be replaced by any of the ions in fast exchange, especially by hydrogen ion, to cause their solubilization in water. This process can make lead, cadmium, and aluminum soluble and available for bioconcentration in food chains and in drinking water sources to which humans are exposed. This must be considered in terms of total exposure to aluminum and aluminum compounds.

In acidic lakes, aluminum is of special concern because it is very abundant in sedimentary rocks (i.e., over 5%). In fact, this element is more abundant than iron in the earth's surface (*59,60*). Acid rain provides the increase in hydrogen ion concentration, which in turn increases the concentrations of soluble aluminum containing chemical species in water. Furthermore, absorption and neurotoxicity of aluminum are enhanced by low dietary calcium and magnesium (*61*). Acidic soils are often deficient in these alkaline earth metals.

The bioaccumulation of mercury occurs in acid lakes by an entirely different mechanism. Inorganic chemistry is introduced as a result of atmospheric deposition. Once present in soils and sediments, such inorganic complexes of mercury are biomethlylated to give the neurotoxins methylmercury and dimethylmercury. Methylmercury is produced in sediments and soils under acidic conditions, whereas dimethylmercury is produced under alkaline conditions. The details of this mercury cycle are very well understood at the biochemical level. Most of the chemical species of mercury, which are present in acid lakes, have been detected and analyzed by sophisticated analytical techniques. This is not true for the analysis of aluminum-species where the predominant chemical species in acidic waters and in biota are not yet understood.

Mercury

Toxic Effects of Methylmercury in Man. The human toxicology of methylmercury is well described in the literature due to catastrophic poisonings (fish) in Japan in the 1950s and 1960s and to a large poisoning (treated seed) in Iraq in the winter of 1971-72. Studies on a number of cases of industrial poisoning have also contributed substantially to the understanding of the toxic effects of methylmercury on man (*62*), primarily the damaging of the nervous system. The main areas affected are associated with the sensory, visual, and auditory functions and those areas concerned with coordination, especially the cerebellum. The earliest effects are nonspecific symptoms, such as complaints of paresthesia, malaise, and blurred vision. Subsequently, signs appear such as concentric constriction of the visual field, deafness, dysarthria, and ataxia. In the worst cases, the patient may go on to coma and ultimately death. In less severe cases, some degree of recovery occurs in each symptom; this is believed to be a functional recovery that depends on the compensatory function of the central nervous system. The subjective complaint of paresthesia was found to be a permanent symptom with patients exposed in the Japanese outbreak, whereas in the Iraq outbreak, paresthesia in many cases was transient. The reason for the difference is not known.

Dose-effect and dose-response relationships for methylmercury compounds in man have been presented and evaluated previously (*63,62*). The most recent analysis of the Iraq data has been published by Nordberg and Strangert (*64–66*). This analysis took into account not only the individual range of thresholds to such symptoms as paresthesia but also the interindividual variation in whole body biological half-times. These two distributions were combined to give an overall estimate of the risk of paresthesia for a given steady state daily intake of methylmercury. Their calculations indicated that an intake of 50 μg/day in an adult person gives a risk of about 0.3% of the symptom of paresthesia, whereas an intake of 200 μg/day would give a risk of about 8% of symptoms of paresthesia.

The range of individual intakes of methylmercury in the United States is not known. With reference to Table 1, a Pike consumer would need to ingest about three times the average amount to approach a daily intake of 50 μg mercury assuming an average mercury level in Pike of 1 μg Hg/g wet weight. However, these estimates of risk apply only to adults. Observations on both human subjects and experimental animals indicate that the developing central nervous system is more sensitive to damage from methylmercury than the adult nervous

Table 1. Fish and shellfish consumption in the United States (September 1973-August 1974).[a]

	Rank	lb/yr	% of total by weight	Number of actual users (millions)	Mean amount per user, g/day
Total		2957	100.0	197	18.7
Tuna (mainly canned)	1	634	21.4	130	6.1
Unclassified (mainly breaded, including fish sticks)	2	542	18.4	68	10.0
Shrimp	3	301	10.2	45	8.3
Ocean perch[b]	4	149	5.0	19	9.7
Flounder	5	144	4.9	31	8.6
Clams	6	113	3.8	18	7.6
Crabs/lobsters	7	110	3.7	13	10.6
Salmon	8	101	3.4	19	6.7
Oysters/scallops	9	88	3.0	14	7.8
Trout	9	88	3.0	9	12.3
Cod[b]	11	78	2.7	12	8.1
Bass[c]	12	73	2.5	7.6	12.0
Catfish[c]	12	73	2.5	7.5	12.1
Haddock[b]	12	73	2.5	11	8.6
Pollock[b]	15	60	2.0	11	6.8
Herring/smelt					
Sardines	16	54	1.8	10	6.7
Pike[c]	17	35	1.2	2.5	17.4
Halibut[b]	18	32	1.1	5.0	8.0
Snapper	18	32	1.1	4.3	9.3
Whiting	20	25	0.9	3.2	9.7
All other classified		152	5.1		

[a] EPA data.
[b] Mainly imports.
[c] Freshwater.

system. The first indications came from the outbreak of methylmercury poisoning in Minamata, Japan, in the 1950s, when it was found that mothers who were slightly poisoned gave birth to infants with severe cerebral palsy (*67*).

Subsequent studies on animals confirm the increased sensitivity of the fetus. In the Iraq outbreak in 1971–72 cases of severe damage to the central nervous system in infants prenatally exposed were also reported. More recent follow-up studies in Iraq have indicated a milder syndrome at lower exposure levels. In fact, it has been possible to demonstrate a relationship between the maximum hair level in the mothers during pregnancy and the frequency of abnormalities in their infants.

The clinical picture was dose-dependent. In those who were exposed to high maternal blood levels of methylmercury, the picture was of cerebral palsy indistinguishable from that caused by other factors. Microcephaly, hyperreflexia, and gross motor and mental impairment sometimes associated with blindness or deafness was the main pattern (*68*). Milder degrees of the affliction were not easy to diagnose during the first few months of life but they became clear with later times. The cases showed mainly psychomotor impairment and persistence of pathological reflexes. The mildest cases had findings quite similar to the findings in the minimal brain damage syndrome (*68*). The frequency of mental retardation in infants may be correlated with maximum hair levels in the mother. Effects are detectable in prenatally exposed infants with maternal hair levels substantially lower than those associated with the onset of signs in adults.

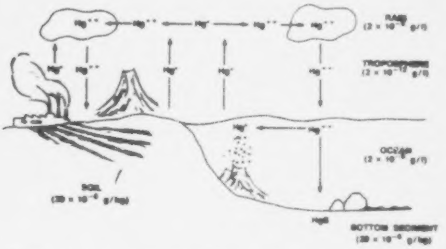

FIGURE 1. A schematic representation of the global cycle of mercury. This scheme is based on reviews by NAS (*100*), Nriagu (*101*), and Lindquist et al. (*69*).

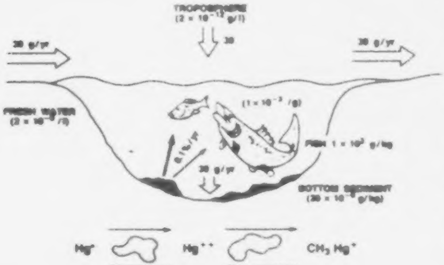

FIGURE 2. A schematic representation of the biomethylation of inorganic mercury and the accumulation of methylmercury in aquatic food chains. The diagram represents a lake surface over 1 km. The open arrows indicate net movement of mercury in grams per year. The other figures give the concentration of mercury in air, water and sediment. The figure is adapted in part from Jernelov et al (*69*).

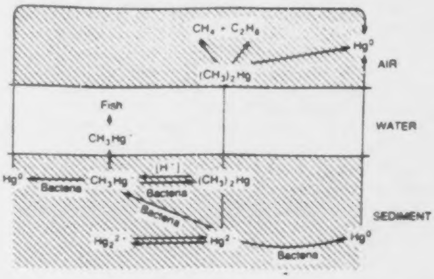

FIGURE 3. A biogeochemical cycle involving bacterial methylation and demethylation of mercury. Adapted from Fig. 3.1 of NAS (*100*).

Role of Acid Precipitation in Mobilization and Transformation of Mercury to Methylmercury. There is mounting evidence that acid precipitation leads to higher levels of methylmercury in edible tissues of freshwater fish (*69*). To appreciate the mechanisms that underly this linkage, it will be useful succinctly to summarize the fate of mercury in the environment. Two cycles are involved: one is global in scope and inorganic in nature; the other cycle is local and biological. The global cycle (Fig. 1) involves the emission of elemental mercury vapor from land and water surface and from anthropogenic sources, especially coal-burning power stations. The anthropogenic contribution (of the order of 3000–5000 tons per year) is probably about 25% of the total emission to the atmosphere. Long distance transport of the elemental vapor occurs in the atmosphere; its residence time is on the order of years. A small fraction of the mercury in the atmosphere is in the water-soluble form. Its precise chemical species is not yet known. This form is returned to the earth's surface in rain water and possibly by dry deposition. Its residence time is of the order of a few days. Bodies of fresh water will receive soluble mercury directly from the atmosphere and indirectly from water run-off from land. A balance study on Swedish lakes indicated the direct and indirect contributions were about equal (Fig. 2). In the water phase, the soluble mercury may be reduced back to metallic mercury and evaporate to the atmosphere. The remainder attaches to sediment. At this point the biological cycle operates on mercury. Inorganic mercury attached to sediment becomes a substrate for microorganisms that produce mono- and dimethylmercury (Fig. 3). The monomethyl species is avidly accumulated by fish and increases in concentration at higher trophic levels of the aquatic food chain (Fig. 3). Concentrations of methylmercury are highest in the tissue of large predatory fish such as northern pike, lake trout, and bass. The levels of methylmercury present in the water phase are extremely low, probably less than 10^{-11} g/L, whereas the concentration in muscle of northern pike may be as high as 10^{-3} g/kg representing a large bioconcentration factor of one hundred million-fold.

Investigators in Sweden noted unusually high concentrations of mercury in pike in lakes that did not receive any known direct discharge of mercury from anthropogenic sources. Furthermore, the level of methylmercury in fish tissue was statistically correlated with the pH of the water. In the pH range of 5–7, the methylmercury in fish rose as the pH fell. In extremely acidic water, below pH 5, lower mercury levels were seen (Fig. 4). Studies in other countries affected by acid rain, e.g., Norway and Canada, have also noted fish in acidic water tend to have higher methylmercury levels.

Many factors are believed to influence methylmercury levels in fish of which pH is only one. The mechanism of the pH effect is not yet fully understood. Several possible mechanisms have been suggested: acidic precipitation may remove mercury from the atmosphere more effectively than neutral pH. The rate of methylation of inorganic mercury by microorganisms is pH dependent with the maximum rate formation of monomethylmercury occurring at lower than pH 6. The pH influences the species of methylmercury formed by the microorganisms, a higher pH favoring the formation of the insoluble and volatile dimethylmercury which would not be accumulated readily in fish but rather vaporized into the atmosphere (Fig. 3). A reduced pH should favor the presence of a divalent ionic mercury in water, reducing its presence in complexes and chelates, and therefore making mercury more available for methylation reactions. The total biomass in an acidic lake is usually lower than in a neutral lake. Thus, since most of methylmercury is present in the biomass, one would expect its concentration to be necessarily higher in the biomass (including the fish) in the acidic lake.

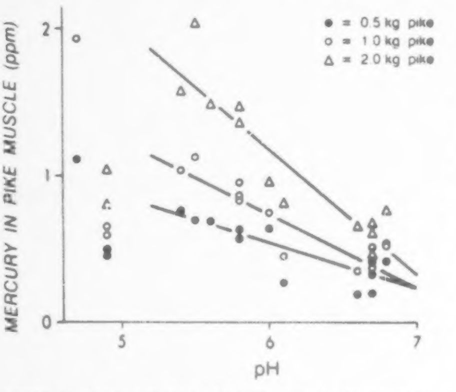

FIGURE 4. The concentrations of total mercury in pike (muscle tissue) as a function of pH. Regression lines were drawn for three groups of fish distinguished by body weight (0.5, 1.0, and 2.0 kg) over the pH range 5 to 7. Adapted from Fig. 3 of KHM. Report No. 192 (*102*).

The consequences of elevated methylmercury levels in freshwater fish may be evaluated from two points of view. First, the current Federal and state guidelines will be enforced, thereby leading to the blacklisting of lakes and rivers having unacceptably high concentrations of mercury in fish. This has occurred in Scandinavia, where there is a Federal action level of 1 μg Hg/g wet weight of fish muscle—the same as the level of the U.S. Food and Drug Administration. The second viewpoint is that human intake of methylmercury will increase. Fish and fish products are the dominant if not only sources of human intake of methylmercury.

The U.S. Department of Commerce (*70*) conducted a survey of over 25,000 individuals representative of the U.S. population with the intention of determining the intake of methylmercury from fish. On a per weight basis, consumption of tuna far exceeds that of other species of fish in the U.S. (Table 1). However, since the actual number of users or consumers of tuna fish is also very high, the amount of tuna consumed per user is not dramatically different than the consumption per user of other species of fish. It is of interest to note that the species with highest consumption per user is northern pike, having a value of 17.4 g/day; species of freshwater fish, catfish, bass, and trout are next highest in per user consumption at about 12 g/day.

Lead. Lead is probably the most ubiquitous toxic metal, and its distribution in the environment, particularly its presence in media that contributes to human exposure, air, water, food, is in large part the result of man's activities. It is clear that the acid rain phenomenon contributes to this problem in a number of ways, but the relative significance of acid rain in a quantitative sense is not yet certain.

Toxicity of Lead. A number of chronic subtle and overt biological effects of lead in humans have been well studied and documented. These include effects on heme biosynthesis and erythropoiesis, central and peripheral nervous system toxicity, kidney effects, derangement of Vitamin D metabolism, and essential trace metal metabolism such as iron, calcium, and zinc. However, it is not possible to quantitate human toxicity risk for lead due to long-term acid precipitation simply because it is not possible to quantitate the potential increase in lead exposure attributable to this factor. But it is possible to rank the various effects of lead across a gradient of increasing human exposure, as indexed by some biological measure such as blood lead, and, if we are at some time able to identify the contribution of the acid rain phenomenon to increases of lead in the environment, we might then be able to measure the impact of the acid rain phenomenon on the human health effects of lead.

Ranking of health effects of lead must be done with that segment of the U.S. general population at most risk for the adverse effects of lead: preschool children. The threshold for effects of lead occur generally at a lower index of exposure in preschool children than adults (*71,72*). These apparent "thresholds" or lowest observable effect levels are given in Table 2. While basic understanding of some of these effects is still under study, it can be seen that more than one effect may occur at even moderate levels of lead exposure. Furthermore, pediatric population surveys, such as the National Health and Nutrition Evaluation Survey (NHANES II), have shown that there are relatively large numbers of children, particularly those in urban areas, whose blood lead values are at or approaching some of the threshold categories in Table 2 (*73*). For example, NHANES II tabulations show that 45.3% of black children aged 6 months to 5 years have 20–29 μg Pb/dL of blood, 9.2% have 30–39 μg Pb/dL and 1.7% have values higher than 40 μg Pb/dL. It is clear from Table 2 and these percentage distributions that the superimposing of any additional lead exposure factor, such as any due to the acid rain phenomenon, will have a significant impact on these percentages by shifting children to higher exposure categories.

Contributions of Acid Rain to Exposure of Children to Lead. The general population, including pregnant women and children, receives its major exposure to lead through lead content of food and water. In addition, children are further exposed to significant amounts of lead in soil, dust, and paint because of their behavioral relationships to these sources, e.g., hand-to-mouth contamination. Acidification of drinking water increases the solubility of lead in the water. More than half of the U.S. population living in year-round dwelling units receive its drinking water from municipal or private supplies derived from surface and ground water (*74*). Lead may be mobilized from sediments and soils to bodies of water which may serve as sources of drinking water. Davies and Everhart (*75*) have calculated that lead solubility in soft, acidic water can reach potentially toxic levels, ca. 500 μg PbL, while Lazrus and coworkers (*76*) estimated that soft waters could mobilize significant levels of lead in surface runoff in the northeastern U.S. at values of pH which are presently attainable from acid precipitation in this area of the U.S.

Relatively acidic water entering a plumbing system prevents the buildup of a normally protective calcium carbonate plaque in plumbing and permits ongoing dissolution of lead. This problem is most acute in older urban areas of the U.S. such as New England where lead piping itself may be in use (*77*), but will also exist to some degree with copper plumbing having lead solder for sealing of joints (*78*). A sizable data base exists for assessing potential impact of acidic drinking water. Studies of the problem in Glasgow, Scotland, where

Table 2. Lowest observable effect levels in young children for lead.[a]

Lowest observed effect level (lead in blood, μg Pb/dL)	Effect observed	Significance
10	ALA-D inhibited Py-5-N inhibited	Accumulation of ALA, disturbed heme biosynthesis Disrupted pyrimidine metabolism in red blood cells
15–20	EP elevation	Signals reduced heme formation in tissues and general mitochondrial injury
15–20	EEG disturbances	Indicates central nervous system dysfunction but the significance in terms of performance is presently unclear
15–20	Reduced 1,25-(OH)$_2$ vitamin D synthesis	There is disturbed absorption and availability of calcium for essential metabolic needs
30	Reduced nerve conduction velocities in adults, probably at this level in children	This is an indication of peripheral nervous system dysfunction
40	Reduced hemoglobin Increased urinary ALA Elevated coproporphyrin	These are indices of significant heme biosynthesis impairment
	Cognitive deficits[79]	Deficits in intelligence and ability to learn at this level of lead are presently being debated
50 and above	Cognitive deficits, renal dysfunction and overt signs of neurotoxicity	Entering the range of overt toxicity of lead to a number of organ systems

[a] Abbreviations: Pb, lead; ALA-D, aminolevulinic acid dehydratase; Py-5-N, pyrimidine-5'-nucleotidase; ALA, aminolevulinic acid; EP, erythrocyte protoporphyrin.

levels of lead in drinking water can reach 500 μg PbL because of soft, acidic water and lead plumbing, have shown that these levels of exposure can be toxic (*79,80*).

A further consideration with acid precipitation is the corrosive effect or deterioration or weathering rate of outside surfaces containing paint of high lead content. This weathering process is not restricted to deteriorated housing in inner urban areas of the U.S. but can also occur in rural areas as well. It is known that significant external weathering of painted surfaces over time is an active process (*81,82*), and there is potential for acid precipitation in hastening this process with concomitant transfer to soils and dusts in contact with children, since a common ingredient in high lead paint is basic lead carbonate.

Finally, it must be emphasized that children take in more lead than adults on a unit weight basis, absorb more of the intake, and also retain a higher percentage. Hence, drinking water used in formulae or other food preparation, as well as beverage, would pose a proportionately greater impact on this age group in terms of lead content changes associated with acid precipitation.

Cadmium

Cadmium Toxicity. The major adverse human health effect associated with long-term low level ingestion of cadmium is renal disease (*83*). Although inhalation of cadmium is known to cause lung disease and possibly cancer of the lung, the potential contributions of cadmium to body accumulations are more likely to be by ingestion and not inhalation. Current understanding of cadmium toxicity is that nearly all cadmium ingested over a lifetime is retained; the biological half-time is probably more than 30 years. Accumulation is greatest in renal cortex and it has been learned from exposed human populations and experimental animals that kidney disease may occur when a critical level of cadmium is reached in the kidney cortex. The actual level in the kidney that causes disease and the mechanism or pathogenesis of the disease is still being studied, but much is known. Another factor in the cadmium problem is that there is no acceptable method for removing this metal from the body as there is for most other toxic metals. Therefore, from a public health viewpoint, it is prudent to be particularly concerned about activities that will add to human exposures.

Role of the Acid Precipitation Phenomenon on Human Exposure to Cadmium. Those segments of the U.S. population at increased risk to the adverse effects of cadmium are the elderly, cigarette smokers, and individuals with unusual dietary habits, particularly vegetarians. Cadmium, like lead, is an element which accumulates in the human body. Unlike lead, however, this accumulation is only associated with vital organs such as the kidney and it is thus difficult to forestall adverse effects due to such accumulation by other than a policy of exposure prevention. Cadmium, therefore, epitomizes an agent whose control is of necessity a prospective process; and the impact of long-term acid precipitation needs to be considered in this.

There are at least three routes for long-term impact of acid precipitation on human exposure to cadmium which should be considered. As with lead, relatively acidic water in plumbing systems has the potential to mobilize cadmium from soldered joints of copper plumbing. While the degree of this problem is not that of lead (see above), available data support the notion that it can be a cadmium exposure risk factor. For example, Deane et al. (*84*) reported that 7% of households studied in Seattle had tap water cadmium levels which exceeded the U.S. Public Health Service standard of 10 μgL for cadmium. The Seattle water supply is quite soft. A potentially greater problem may reside in the mobilization of cadmium from crop soils which are dressed with cadmium-containing phosphate fertilizer into various crops because of the long-term impact of acid precipitation on such lands. The crops include not only food categories but other economically important production, particularly tobacco. Tobacco and leafy food vegetables are particularly effective scavengers of soil cadmium under conditions of reduced pH. The amount of land involved is very large and there are presently no regulatory guidelines for the use of cadmium-containing phosphate on such lands (*83*). A third consideration relates to the land application of municipal sewage sludges, which is increasingly being viewed as a disposal option of last resort (*83*). While regulations attending such land spreading include liming to immobilize the cadmium and other toxic elements, the long-term impact of acid precipitation on these control measures can be deleterious. An additional factor is the potential for leaching of cadmium from waste dumps.

Aluminum

Aluminum, the most common metallic element, comprises 5% of the earth's crust. For the most part, aluminum is largely present in insoluble, and thus biologically unavailable, forms. Among the effects of acid rain is the solubilization of significant amounts of aluminum from the soil resulting in increased levels of the element in local lakes and streams. The possible toxic effects of these elevated aluminum levels on fish and vegetation has been the subject of research and there is evidence available that in this setting it can indeed exert a harmful effect on both flora and fauna. In the present state of scientific knowledge, we cannot make any definitive statements as to the potential human health effects of acid rain with respect to aluminum.

Aluminum is not known to be utilized in any natural biologic process and is generally considered to be relatively nontoxic to man. However, within the past several years, aluminum has been implicated in the pathogenesis of several human disorders. Most of these conditions occur in patients with chronic renal failure. The best characterized is a condition referred to as dialysis encephalopathy or dialysis dementia (*85*). This disorder is characterized by progressive speech disturbance, dementia, and convulsions. The brain tissues, muscle and bone of affected patients show markedly elevated aluminum content. It is generally fatal within six months, although some patients have had clinical improvement following chelation therapy (*86,87*). In general, the aluminum is thought to originate from either dialysis fluid containing excess aluminum or from excess oral intake (*88*). Nondialysis patients with this condition have been found among children with renal failure who were taking oral aluminum hydroxide preparations (*89,90*).

Other aluminum-related problems are seen in patients with chronic renal failure. Osteodystrophy occurs in patients who deposit large amounts of aluminum in their bones (*91,92*). These patients can develop spontaneous fractures and frequently will also have evidence of encephalopathy. One study has shown that the tap water of renal patients with the highest incidence of fractures and encephalopathy had concentrations of calcium and fluorine which were lower and concentrations of aluminum and magnesium which were higher than those in the water of patients without these complications (*93*).

Aluminum has also been considered to play a possible role in the etiology of Alzheimer's Disease. Aluminum salts can induce lesions in the nervous system of the cat and rabbit that are similar, but not identical, to those seen in the brains of Alzheimer's Disease patients (*94,95*). The studies of Crapper and coworkers have shown evidence of increased amounts of aluminum in the brains of individuals dying of Alzheimer's Disease when compared to nondemented controls (*96*). Attempts to reproduce this finding have produced varying results and remain controversial (*97*). Perl and coworkers have evaluated this question on a cellular level, using precise electron probe methods. Their data (*98*) indicate that aluminum accumulation is found in those neurons which demonstrate the presence of neurofibrillary tangles (one of the characteristic microscopic lesions of Alzheimer's Disease).

Similar findings have been reported in neurons containing neurofibrillary tangles in the brains of the Chamorro natives living on the island of Guam (*99*). The Chamorros have been extensively studied over the past 35 years in an effort to explain their remarkable tendency to develop neurofibrillary tangles associated with amyotrophic lateral sclerosis and Parkinsonism with dementia. Extensive data collected on Guam strongly suggests that the unusual tendency towards neurodegenerative disorders is related to local environmental factors and that aluminum accumulates in the brains of affected individuals.

Another recent study demonstrates that aluminum can affect the permeability of the blood-brain barrier to small peptides, a change that may be related to the primary defect responsible for senile dementia (Alzheimer's Syndrome) (*61*).

The present state of knowledge indicates that aluminum in our environment as well as aluminum-containing products constitutes little, if any, risk of acute toxicity to the healthy population. However, those with chronic renal failure, particularly those undergoing renal dialysis, are especially vulnerable to the toxic effects of this element. Whether this risk significantly increases through the liberation of increased amounts of aluminum by the action of acid rain is a debatable question. There is certainly a great deal more aluminum within a single antacid tablet or slice of American cheese than is present in a gallon of stream water coming from an acid rain-washed region. The problem is that one cannot rely purely on a simple parts-per-million concentration of the element. We know very little about the various chemical species in which aluminum exists in nature and their potential bioavailability.

We have even fewer scientific data available with respect to the potential long-term effects of exposure to aluminum in our environment. Although aluminum has now been demonstrated within the damaged nerve cells associated with Alzheimer's Disease, it is still unclear if this phenomenon has etiologic significance. The data from Guam suggests that local environmental factors can play an important role, apparently acting through soil and water supply. Again, details of aluminum speciation on the island are lacking. Factors that allow aluminum to enter the nervous system of one individual and not another are not known. Field data indicate that one of the effects of acid rain is to increase the bioavailability of aluminum to flora and fauna. How high that concept extends up the biologic ladder is unknown. The possibility that it might extend to man is hypothetical, yet is certainly scientifically plausible.

Conclusions

Adverse human health effects, namely acute and chronic respiratory effects, can occur from the predeposition phase of the acid phenomenon due to inhalation of acidic particles and gases. State-of-the-art methodology to evaluate these effects is just now being applied to this question.

The major postdeposition effect of the acid rain phenomenon is to acidify water, increasing solubility and subsequent human exposure to mercury, lead, cadmium, and aluminum. Acidification increases bioconversion of mercury to methylmercury, a highly toxic compound, which accumulates in fish, increasing the risk to toxicity in people who eat fish.

Increase in water and soil content of lead and cadmium increases human exposure to these metals which become additive to other sources presently under regulatory control. The potential adverse health effects of increased human exposure to aluminum is not known at the present time.

Deficiencies in the identification of the contribution of predeposition of air pollutants and postdeposition mobilization of toxic metals to the recognized potential health effects of the involved toxic substances are due to the fact that scientists have not addressed these specific questions.

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Appendix 2

Conference on Health Effects of Acid Precipitation

November 15-16, 1984

National Institute of Environmental Health Sciences
South Campus Conference Room 101
Research Triangle Park, North Carolina

Thursday, November 15, 1984

8:30 a.m.	Comments - Objectives of Conference	Dr. Robert Goyer, NIEHS
8:45 a.m.	Overview - Acid precursor pollutants; emission, transport and deposition	Dr. Jack Durham, Env. Protection Agency
Session I	- Health Effects - Pre-depositional Phase of Acid Precipitation	Dr. Benjamin Ferris, Chairman
9:00 a.m.	Problems in the estimation of human exposure to components of acid precipitation precursors	Dr. Benjamin Ferris, Harvard Sch. Public Health
9:30 a.m.	Deposition of acid droplets in respiratory tract	Dr. Ted Martonen, Northrop Services, Inc.
10:00 a.m.	Effects of inhaled acids on respiratory tract defense systems	Dr. Richard Schlesinger, New York University
10:30 a.m.	Coffee Break	
10:45 a.m.	Effects of inhaled acids on lung mechanics	Dr. Mark Utell, University of Rochester
11:15 a.m.	Analysis of health effects resulting from population exposure to acid precipitation precursors	Dr. Haluk Ozkaynak, Harvard University
11:45 a.m.	Potential risks to human health from "acid fog"	Dr. Jack Hackney Univ. of S. California
2:15 p.m.	Lunch	
Session II	- Effects of Acid Precipitation on Mobilization, Transport and Speciation of Toxic Metals	Dr. William Sharpe, Pennsylvania State Univ.
1:15 p.m.	Corrosiveness of water and leaching of metals	Dr. William Sharpe, Pennsylvania State Univ.
1:45 p.m.	Effect of acid precipitation on water pH and metal bioavailability	Dr. Pamela Stokes, University of Toronto

Friday, November 16

Session IV - Summarization of Sessions I, II, & III		Dr. Robert Goyer, Chairman
1:00 p.m.	Discussion of Session I - Estimates of exposure and human health effects to air pollutants related to acid rain	Dr. Morton Lippmann, New York University
2:00 p.m.	Discussion of Session II - Effect of acid rain on mobilization/transport/speciation of post-deposition of pollutants (toxic metals), including effects of corrosiveness, and leaching of metal content of soil/water/vegetation/food	Dr. John Wood, Gray Freshwater Biological Institute
3:00 p.m.	Discussion of Session III - Impact of effects of acid precipitation on toxicity of metals	Dr. Gunnar Nordberg, University of Umea, Sweden

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Appendix 3: NIEHS Research Program to Determine Health Effects of Acid Rain and Highlights of Accomplishments and Plans Addressing Research Needs to Determine Health Effects of Acid Rain

I. Research to Study Health Effects of Acidic Air Pollutants

The National Institute of Environmental Health Sciences (NIEHS) is currently sponsoring 18 research projects concerning effects of acidic air pollutants on human health. Studies cover a range of approaches including study of people in the ambient environment, people in chambers with controlled exposures, and a variety of animal models and *in vitro* studies. Overview and comment is provided for a number of these projects.

A. Studies Primarily Directed to Determine Health Effects of Acid Aerosols and Sulfur Compounds and Particulates

Particular attention should be given to the design, accomplishments, and research plans of one of these projects, the Harvard Six Cities Study, because it is an ongoing project that relates the health of selected human populations in cities with differing levels of air pollutants from fossil fuel combustion and constituents of acid rain.

Six cities were selected for study (Steubenville, Ohio; St. Louis, Missouri; Watertown, Massachusetts; Kingston/Harriman, Tennessee; Topeka, Kansas; and Portage, Wisconsin) because they represent a spectrum or gradient in severity of air pollution. Steubenville and St. Louis historically have air pollutant concentrations exceeding the National Primary Air Quality Standards, whereas Portage and Topeka are considerably below these standards. Also, the four cities with the highest pollutant levels (Steubenville, St. Louis, Kingston, and Watertown) are located in the "acid rain plume," an area extending from the midwestern portions of the United States to New England. Air pollution data are collected from outdoor and indoor environments and correlated with measures of pulmonary function and lung disease in selected adults and children. Populations from two other cities, Portage, Wisconsin, and Topeka, Kansas, are also being studied. These cities historically have lower levels of the air pollutants, sulfur dioxide (SO_2), total suspended particulates (TSP), and suspended sulfates (SS) than do the other four cities. An important aspect of the study is that it is "longitudinal" in design, that is, the same subjects, children and adults, are identified and followed periodically into the future. Parameters of growth of children can also be correlated with air pollutants.

The study is in its twelfth year and results to date show that frequency of cough in children is associated with the average of twenty-four hour mean concentrations of all three air pollutants during the year preceding their health examinations. Rates of bronchitis and a composite measure of lower respiratory illness are significantly associated with average particulate concentrations. In analyses restricted to lifetime residents, these outcomes were significantly associated with measures of lifetime mean TSP concentrations. Pulmonary function parameters were not associated either with pollutant concentrations during the year preceding the pulmonary function test or, for lifetime residents, with lifetime average concentrations. These results suggest that, for preadolescent children, exposure to moderately elevated concentrations of these pollutants may increase risk for bronchitis and other respiratory disorders, but have little or no effect on pulmonary function at least at the present time. The strong association between total sulfate concentrations and other measures of fine particles and symptoms of bronchitis suggest that exposure to these pollutants at the levels measured do have observable health effects.

One component of Harvard's Air Pollution Health Survey deals with development of an operational monitoring system for sulfate/sulfuric acid aerosol measurements. This was a research need emphasized in the NIEHS workshop report on acid rain. The system will be deployed in each of the six cities participating in the study. The monitoring is currently in effect in two of the six cities: Harriman, Tennessee, and Watertown, Massachusetts. This monitoring system when fully operational in the six cities will allow for apportionment of the total sulfates acidity to sulfuric acid and ammonium sulfate and provide information for studying human exposures to these two strong acids as present in acid rain. The combined data will provide a valuable measure of population exposures in conjunction with daily indices of acute upper and lower respiratory disease in each participating community.

B. New York University Studies

A second large study relating acid rain pollutants to human health is being conducted by the NIEHS Environmental Health Sciences Center at the Institute of Environmental Medicine, New York University. Investigators at this center have designed and developed a series of experiments in which rabbits as the animal model are exposed to ambient acids (related to acid rain) and the resultant effects on lung structure, respiratory mechanics, and specific pulmonary function are determined and correlated. Preliminary studies have demonstrated the effect of sulfuric acid aerosols on bronchial mucociliary functions to be similar in rabbits and humans. The rabbit animal model for the proposed studies was thus validated. Single short-term exposure to acid aerosols resulted in an accelerated tracheobronchial clearance upon low concentration exposure and retarded clearance after high concentration exposure as measured by clearance of radio-labeled latex particles. With these preliminary results, the investigators intend to conduct a thorough examination of lung histopathology, lung function as mucociliary clearance, and some measures of respiratory mechanics as a consequence of acid aerosol exposure of a variety of concentrations and durations of exposures. These studies involve both human and animal models.

Investigations with humans will be conducted in an environmental chamber providing controlled exposures to low-level acid pollutants in a double-blinded fashion. The subjects to be studied will be asthmatics and those with chronic bronchitis, pulmonary emphysema, or other chronic obstructive lung diseases. Patients with acute respiratory viral diseases will also be studied. Pollutants to be included will be sulfuric acid aerosols, ammonium sulfate aerosols, sodium chloride aerosols, and mixtures of sulfuric acid aerosols with nitrogen dioxide. Initial studies will use aerosols of 0.8 micrometers at concentrations of 50 to 75 micrograms per cubic meter and nitrogen dioxide at 0.20 ppm. Subsequent studies will involve increasing aerosols size up to ten micrometers to maximize bronchial deposition, or increasing relative humidity from thirty percent up to eighty percent. The experimental design will include exercise, carbachol challenge tests, and the measurement of endogenous ammonia in expired breath. Respiratory effects will be measured with pulmonary function tests that include airway resistance, and thoracic gas-volume flow-volume curves.

These studies should provide information toward establishing air quality standards that will protect populations particularly susceptible to low-level acidic pollutants.

The human studies will be complemented with studies in animals to investigate certain mechanistic aspects. Specifically, animals will have exposures similar to those of humans, but at somewhat higher concentrations. Endotracheal exposures will allow a differentiation between effects on conducting airways and alveolar defense systems. Measurements will include tracheobronchial permeability, histamine content, phagocytic activity of alveolar macrophages, alveolar epithelial permeability, and cellular components in both bronchial and lung lavage fluids. These animal studies are designed to elucidate mechanisms of action that could not be determined in humans.

C. Rancho Los Amigos Hospital Study, Downey, California

A study is underway by investigators in Southern California to determine short-term, health-related response in human volunteers breathing atmospheres containing "acid fog." The exposure atmospheres are designed to resemble Southern California fogs and eastern fogs of the type associated with past air pollution disasters. Healthy human volunteers as well as volunteers suffering with chronic respiratory disturbances will be evaluated during and after exposure to the controlled atmospheres.

D. Massachusetts Institute of Technology (MIT) Environmental Health Center Projects

At this NIEHS-supported Environmental Health Sciences Center, a number of studies on health effects of components of acid rain are underway. The effects of exposure to sulfuric acid mist upon the mucociliary clearance system is being examined in rabbit as an animal model. Clearance during the exposure period and for a pre-determined time afterward will be monitored by serial external measurements of an inhaled radioactively-tagged tracer aerosol. The study will provide information on the quantitative and temporal changes in mucociliary clearance and airway histology as these may relate to the pathogenesis of chronic bronchitis due to sulfuric acid exposures.

Particle induced x-ray emission is being employed in a selected human population to determine the effects on pulmonary function of exposure to low concentrations of gaseous SO_2 and fine aqueous aerosol droplets. Using these methods, it was demonstrated that one-half to three hour exposures to combinations of $SO_2 < 1$ ppm and aqueous aerosol droplets caused a significant increase in closing volume relative to vital capacity over that measured for non-exposure controls.

Prior studies in rats have shown that sulfur dioxide (SO_2) may potentiate the pulmonary carcinogenicity of polycyclic aromatic hydrocarbons (PAH), in particular benzo(a)pyrene (BP). Since man is exposed simultaneously to PAH and SO_2 in urban and polluted atmospheres and may, therefore, be at increased risk, a study is underway to investigate whether SO_2 alters the pulmonary metabolism of BP so as to increase exposure of lung tissues to toxic intermediates arising from BP.

Controlled coal combustion is being carried out in the laboratory to characterize the ultrafine combustion aerosols and sulfur dioxide formed and their effects on laboratory animals. Functional changes following exposure are evaluated by measurement of respiratory mechanics, and measurement of lung volumes. Pathological and biochemical parameters are also being determined. Information on the formation, interaction, and toxicological effects of the ultrafine aerosols and SO_2 are needed to design control strategies related to the combustion of fossil fuels.

E. Other Studies

In one study the effects of route of inhalation (oral versus oro-nasal) of sulfur dioxide and sulfuric acid on pulmonary function and the effect of pre-treatment with bronchodilator drugs on inhibition of SO_2-induced bronchoconstriction are being determined in either male or female allergic adolescents with or without asthma. The objectives of the project are to extend our knowledge of the effects of sulfur oxide air pollutants in susceptible individuals.

In another study, measurement of alterations of pulmonary mechanics in guinea pigs is used as a toxicological tool to evaluate response to irritants. Experiments are designed to furnish additional information in animal toxicology for the data base of air quality criteria for sulfur dioxides and particulates for ozone and for oxides of nitrogen.

Other studies show that mucociliary dysfunction occurs in airways following exposure to pollutant gases such as ozone and sulfur dioxide. The manifestations include loss of cilia, reduced ciliary beating, reduced mucus transport, and secretory tissue hyperplasia. This dysfunction may be exaggerated in allergic airways and may increase allergic airway disease. Studies to understand this phenomenon are being carried out using normal and allergic sheep.

II. Studies Primarily Directed to Effects of Acidic Air Pollutants Composed of Nitrogen Containing Compounds and Oxidizing Agents

A. Effects of Cells Lining Lung Surfaces

One project is studying the effects of the nitrogen oxide components of acid rain and ozone on the chemical composition of cells lining air sacs, the functional cells of the lungs where gases are exchanged with cells in blood.

In another study, it has been shown in preliminary experiments that there is an increase in tracheal and bronchoalveolar permeability to macromolecules following inhalation exposure of rats to ozone. The increased permeability appears to result, at least in part, from the perturbation of tight junctions between cells. It appears that the cytoskeleton is the likely target site for pollutant gases and that it plays a critical role in the modulation of tight junction permeability. These changes will be investigated more extensively in an animal model exposed to ozone and/or nitrogen dioxide.

B. Effects on Macrophages and Cellular Defense Mechanisms (Against Infectious Agents)

Several studies are underway to further investigate the suggestive evidence that a number of pollutant gases inhibit pulmonary macrophage phagocytosis. Using a combination of in vivo and in vitro experiments, the action of ozone and nitrogen dioxide on inhibition of phagocytosis is being determined.

The biochemical basis for the deleterious effects of oxidizing air pollutants with particular focus on cell membrane effects is underway and will utilize lung phagocytic cells. The effects of ozone and nitrogen dioxide on the production of superoxide anion radical on the fluidity of the plasma membrane and the electrochemical potential of the membrane will be determined.

C. Relationship of acid rain to emphysema studies are underway to determine the various parameters which influence the development of emphysema in hamsters exposed for long periods of time to NO_2. These include elastin degradation, impaired secretion of elastase by macrophages, and the effect of natural and synthetic protease inhibitors. The information should help to clarify the role of proteases in the neutrophil that are altered by nitrogen dioxide and related to the development of emphysema.

III. Research to Study Health Effects of Toxic Metals

Acid rain through the deposition of acidic materials on water and soil results in the mobilization, transport, and even chemical transformation of toxic metals. These consequences of acid rain, in turn, may increase human exposure to toxic metals by increasing soluble forms of metal in various media (food, water, air, etc.). In some instances, the metal may be transformed to a more toxic form, e.g., inorganic mercury to alkyl (methyl) mercury. A more detailed discussion of effects of acid rain on the potential toxicity of metals to humans is presented in summary papers of the NIEHS Conference on Health Effects of Acid Precipitation.

The NIEHS Extramural Program supports 52 projects concerned with some aspect of the biologic and human health effects of potentially toxic metals. Although some of these projects concern effects of more than one metal, the following comments highlight activities in progress in terms of only the four metals thought to be most affected by acid rain.

A. Research on Health Effects of Excess Exposure to Lead

The consequences of asymptomatic lead exposure in man and the development of rational approaches for their prevention and treatment are matters of continuing importance. Decrease in pH (acidification) increases solubility of lead compounds in water and amounts in living organisms and ultimately in man. Research supported by the NIEHS is concerned with a broad spectrum of scientific issues. These include the assessment of behavioral, reproductive, visual, neurological, gastrointestinal, and renal effects of lead exposure. In addition, research on the clinical assessment and therapy of lead exposure is being supported. Some of the research supported is described in the following paragraphs.

Dr. Robert Bowman at the University of Wisconsin in Madison, Wisconsin, is conducting studies to provide a description of the cognitive syndrome resulting from neonatal lead exposure and to develop test paradigms that are sensitive to the effects of low-lead exposure. This investigator has found that delayed spatial alternation is sensitive in detecting a persistent lead-induced cognitive dysfunction in six-year-old monkeys exposed to lead during their first year after birth. Studies are underway to determine the underlying mechanism of this effect.

Lead exposure can also have adverse effects on reproductive function. Dr. Rebecca Sokol at the University of California Medical Center in Torrance, California, has shown that testicular function and sperm production are affected at low levels of lead exposure. The hormonal mechanisms responsible for these effects have not been fully characterized, but their data suggest that the dominant mechanism of action of lead toxicity is at the level of the hypothalamic-pituitary axis. This investigator is determining the time course, dose dependency, and reversibility of reproductive abnormalities induced in male rats by daily exposure to lead acetate. The ultimate goal of this research is to delineate the mechanism(s) and site(s) of action of lead on the hypothalamic-pituitary-gonadal axis. Dr. Joseph Graziano at the Columbia University in New York, New York, is beginning a study to examine the relationship of chronic lead exposure to adverse pregnancy outcomes, infant development, and infertility. This study draws upon a unique community in Mitrovica, Yugoslavia, which is the site of a heavily polluting lead smelter.

The delineation of the adverse psychological and neurophysiological effects of childhood lead exposure remains a concern. Dr. Arthur Michaelson at the University of Cincinnati, Cincinnati, Ohio, is conducting studies at the cellular and neurochemical levels to assess the basis for the neuropsychological dysfunctions induced by lead. This investigator has proposed that a common mechanism underlies the central nervous system (CNS) neurotransmitter insult following neonatal exposure to lead. The hypothesis which he is testing is that inhibition by lead of the flux of calcium across the nerve terminal during neonatal CNS development will result in a persistent alteration in interneuronal calcium regulation that will be reflected in generalized alteration in transmitter release. This research will establish whether a generalized and persistent alteration in the neuronal calcium regulatory process is the basis of the CNS insult following neonatal lead exposure.

Dr. Carol Angle and associates at the University of Nebraska Medical Center in Omaha, Nebraska, are investigating the multifactorial interaction of lead and the red cell membrane. These investigators have shown that the maximum acceptable blood level (30 µg/dl) for children evokes hemolysis manifested by target cells with decreases in membrane fluidity, osmotic fragility, cell survival, and pyrimidine-5'-nucleotidase activity. The results from these studies may result in a more useful method for assessing low blood lead levels and provide new insight into the biologic effects of lead exposure of the general population as well as that of lead workers and young children.

Dr. Deborah Slechta at the University of Rochester in Rochester, New York, has proposed that juvenile and adult organisms may be more susceptible to lead neurotoxicity than commonly recognized. Recent data from her laboratory indicate that juvenile rats chronically exposed to lead in drinking water at a concentration of 50 ppm (blood lead 20-30 µg/dl) manifest distinctive behavioral phenomena. These appear as markedly elevated rates of responding in operant behavior testing. Studies are underway to determine the underlying mechanism(s) of this phenomenon.

B. Research on Health Effects of Excess Exposure to Cadmium

Cadmium is a widely dispersed toxic trace metal which is becoming an increasingly important environmental pollutant. Cadmium is not readily excreted by the kidney so that exposure results in progressively higher concentrations in body organs, especially liver and kidney. The NIEHS is supporting research to identify and determine the mechanisms of its biological effects, to assess the role of metallothionein in the biological response, and for the development of therapies. Some of the research in each area is described in the following paragraphs.

The mechanism of inhibition of biosignal transmission by cadmium is being investigated by Dr. Rama Sastry at the Vanderbilt University in Nashville, Tennessee. For these studies, two types of biosignal transmissions are being studied: phospholipid N-methylation (PMT) and acetylcholine (ACh) transmission. The PMT pathway is inhibited irreversibly by cadmium. In an effort to determine the mechanism of biosignal inhibition, several specific aims have been identified. The possible protective effects of zinc, cysteine, and metallothionein, the relationship between PMT inhibition and functional activity of tissues, and effects of cadmium on regenerating rat liver will be examined. The studies may help explain the muscle weakness and paralysis, depressed placental function, and general toxic effect on regenerating tissue by cadmium.

Immune functions are also affected by cadmium. Dr. Richard Winchurch and associates at the Johns Hopkins University in Baltimore, Maryland, are investigating which immune functions are altered and the mechanisms of their action. These studies include the investigation of the influence of cadmium on both cellular and humoral immune responses in adult and neonatal mice. In addition, the dose-response relationship for discrete immune functions and the metal and metallothionein content in various lymphoid and non-lymphoid tissue will be determined. Finally, the effects of cadmium on the response to endotoxin will be determined.

Dr. Ernest Foulkes of the University of Cincinnati in Cincinnati, Ohio, is examining the cadmium-induced nephrotoxicity. The nature of this effect, though well known, is not understood. This study focuses on the lesion leading to the aminoaciduria, i.e., the inhibition of amino acid resorption in the proximal tubule. The results so far show that this inhibition resembles a simpler system and may be referred to as uncompetitive inhibition. The significance of this concept has led to a new experimental approach which permits analysis of saturation and inhibition kinetics of amino acid transport without the complicating factors of long equilibrating infusions. The final outcome of the work should be a better understanding of how toxic metals are excreted by the kidney.

One of the consequences of cadmium exposure is the induction of the metallothioneins. These are low molecular weight, cysteine rich, heavy metal binding proteins. However, it is not clear whether the function of the protein is to protect the organism from toxic metal or to store necessary heavy metals for delivery at times and to organs where they are needed. Dr. Gustavo Maroni at the University of North Carolina at Chapel Hill, North Carolina, is investigating the role of metallothionein in protection against cadmium toxicity. This is investigated by obtaining mutants in Drosophila melanogaster, which are unable to produce normal metallothionein, and testing them for their sensitivity to cadmium. Dr. Robert Cousins at the Rutgers University in New Brunswick, New Jersey, is conducting studies to determine the mechanism of metallothionein induction. Polysomal and post-ribosomal poly(A)mRNA will be translated in a wheat germ system and newly synthesized metallothionein will be measured. The mRNA will be obtained from cadmium-fed and cadmium-injected rats and from isolated rat liver parenchymal cells in primary culture previously exposed to various treatments. In addition, the rate of metallothionein synthesis will be measured in rat kidney after injections and oral administration of cadmium.

Studies are underway to develop more efficacious therapies for cadmium toxicity.

C. Research on Biochemical Transformations and Health Effects of Mercury Compounds

One of the most prominent effects of acid rain is the effect of decreasing the pH of lakes and increasing the conversion of inorganic mercury to the more toxic methylmercury. Several studies on the health effects of methylmercury are concerned with neurotoxicity. One such study is directed toward the understanding of the sequential biochemical and early ultrastructural events induced by methylmercury in the cerebellum, in isolated cerebellar purkinge cells, and cell-free protein translation systems. Identification of the mercury-induced biochemical and ultrastructural lesions will provide means for determining sub-symptomatic neurotoxicity.

Another study will determine the effects of methylmercury on the growth and development of fetal brain. These studies are carried out in mice and human brain cells and pregnant mice exposed to mercury. The objectives of the study are to assess, in detail, the changes in development of fetal brain brought about by maternal intoxication of methylmercury.

Using intracellular microelectrode recording techniques and electron microscopy in conjunction with x-ray microprobe analysis, the mechanism of acute toxicity of methylmercury on presynaptic neuromuscular function is being studied in rats and mice. The results are expected to provide answers to questions regarding the mechanism of action of (methylmercury) on synapses, particularly its interactions with the voltage dependent Ca^{2+} channel and with nerve terminal Ca^{2+} buffering systems.

Another study is designed to determine molecular and cellular mechanisms by which congenital mercury exposure of rat fetuses results in smaller offspring and to congenitally expose monkey fetuses in a similar manner to determine the dosage levels and mechanisms producing similar changes in primates and to determine whether these changes alter growth, metabolism or the ontogeny of behavioral characteristics.

D. Research on Health Effects of Aluminum Compounds

Human exposure to aluminum through the environment is increasing due to solubilization in acidic water and possible chemical transformation. The hazard to man from this increased exposure is not understood. One study on aluminum employing rabbits exposed *in utero*, neonatally, during lactation, and as mature animals will assess the neurobehavioral toxicity of this metal at the various stages of development. The results of the study should further our understanding of the interaction between aluminum and some of the biological factors which seem to contribute to aluminum associated diseases such as dialysis encephalopathy and Alzheimer disease.

E. Other Studies Including Effects of Mixtures of Metals

A large multidisciplinary program project grant is focusing on four metals, mercury, lead, cadmium, and manganese, and encompasses investigations of the physical and chemical properties of metals and metal compounds that determine how they enter the body, how they are distributed, are metabolized, the mechanism controlling elimination from the body, and their capacity to impair the vital body processes. Special attention is paid to effects on major organ systems and to genetic factors.

The NA$^+$,K$^+$ATPase is an enzyme of the plasma membrane involved in the regulation of the internal ionic environment of most mammalian cells. Interactions of this enzyme with short-chain alkylmercury compounds, such as methylmercury, inhibit the NA$^+$K$^+$ dependent ATPase activity of the enzyme without inhibiting its partial reactions. The goal of this study is to understand the mechanism and elucidation of the mechanisms.

The effects of heavy metals on the immune system are the focus of two studies: one will determine the effects of metals on the structure and functions of murine lymphocytes to determine the short- and long-term effects of exposure to low levels of metals and will identify health hazards to certain populations and individuals; the second is aimed at an in-depth study of mercury in its various forms in relationship to the induction of autoimmune disease.

Other heavy metal studies include the role of methylation within mammalian tissues in producing toxic effects at the cellular and genetic levels to effect mutagenic manifestations, and the role of methylmercury in inhibition of DNA and RNA synthesis in cultured cells, and the interactions of methylmercury with selenium in various *in vitro* systems of nucleic acid synthesis.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

RESEARCH ON AIDS

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RESEARCH ON AIDS

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RESEARCH ON AIDS

Executive Summary

In House Report No. 99-289, the Committee on Appropriations requested that the NIH prepare and submit a report on how the $70 million provided in the 1986 appropriation within the Office of the Director (OD), NIH, for AIDS research will be used. This document is submitted in response to that request.

After the reductions associated with the Balanced Budget and Emergency Deficit Control Act and the proposed rescission, a total of $53.1 million was available for allocation to the Institutes. Of this amount, we have scheduled the disbursement of $50 million. The NIH believes it is essential to maintain some flexibility to pursue new opportunities and scientific breakthroughs and will therefore hold $3 million in reserve for this purpose. However, all funds will be allocated before the end of the fiscal year. The current allocations by Institute are as follows:

National Cancer Institute	$ 13,450,000
National Institute of Dental Research	1,057,000
National Institute of Allergy and Infectious Diseases	35,527,000
Amount to be held in Reserve	3,041,000
	$ 53,075,000

The programs that would be supported within these allocations are described in detail in the body of the report.

RESEARCH ON AIDS

INTRODUCTION

In its report on the Fiscal Year 1986 budget for the Department of Health and Human Services, the Committee on Appropriations stated:

> "Although the NIH has identified approximately $70.7 million for AIDS research within its amended request, the Committee believes that, in the interests of accelerating the program so that all promising avenues can be pursued, additional amounts are needed. Therefore, the Committee is providing an additional $70 million within the Appropriation of the Office of the Director, NIH, to disburse among the Institutes for new AIDS initiatives and expanded programs.
>
> The Committee requests a report on how the resources provided in the bill will be used, not later than thirty days after its enactment, with periodic updates." (pp. 35-36)

The following report has been prepared by the National Institutes of Health of the Department of Health and Human Services in response to this request.

BACKGROUND

Rapid advances are being made in identifying compounds that have some anti-reverse transcriptase activity in the laboratory. Some of these compounds warrant more thorough study in 1986. Interesting findings in the laboratory leading to the development of new drugs and new therapeutic modalities, as well as leads on viral vaccine development, will also receive additional support. Natural history and epidemiological studies will also be expanded with additional funding. The new initiatives to be undertaken in 1986 with the increased resources were recommended to the NIH Director by the NIH AIDS Executive Committee. This Committee was reconstituted in October 1985, to assist the NIH Director in planning NIH AIDS research initiatives, to recommend the allocation of AIDS resources, and to coordinate both scientific and public policy development. The Committee's membership is comprised of Institute Directors and has been broadened to include each NIH Institute with investments in AIDS research. The Committee is chaired by the Director, NIH, and is co-chaired by the Director, National Institute of Allergy and Infectious Diseases (NIAID), who also serves as the NIH AIDS Coordinator.

After the reductions associated with the Balanced Budget and Emergency Deficit Control Act and the proposed rescission, a total of $53.1 million was available for allocation to the Institutes. The amounts estimated for each Institute, along with the planned allocation, are as follows:

(Dollars in thousands)

	1986 Appropriation	1986 Available After Sequestering	1986 Revised Estimate	1986 With Planned Allocation
NCI	$ 28,441	$ 27,218	$ 27,218	$ 40,668
NHLBI	11,200	10,718	10,718	10,718
NIDR	684	655	655	1,712
NINCDS	1,500	1,435	1,435	1,435
NIAID	27,067	25,903	25,903	61,430
NEI	100	96	96	96
DRR	1,731	1,657	1,657	1,657
Subtotal	70,723	67,682	67,682	117,716
OD	70,000	66,990	53,075	3,041
Total	$140,723	$134,672	$120,757	$120,757

Descriptions of the new initiatives proposed by the individual Institutes to be funded from the additional funds included in the 1986 OD appropriation are provided in this report

PLANNED ALLOCATION OF AVAILABLE FUNDS

NATIONAL CANCER INSTITUTE

1986 Appropriation Estimate	$ 28,441,000
Sequestration	- 1,223,000
Proposed Allocation from OD	13,450,000
Total Estimate	$ 40,668,000

A. DRUG DEVELOPMENT

The NCI new drug development program was initiated by congressional mandate in 1955 in response to a national commitment to develop new drugs for the treatment of metastatic cancer. The resulting organization of the Developmental Therapeutics Program (DTP) of NCI is unique within Government. In essence, DTP represents a self-contained drug industry within NCI with resources to acquire, screen, select, formulate, perform toxicology, and synthesize large-scale bulk pharmaceuticals for new drugs and lead compounds in the treatment of cancer. The track record of this drug discovery program is impressive; the NCI has been responsible for discovery of half the commercially available anticancer drugs since 1955. The Institute proposes to expand this existing system to meet the priority of developing agents with activity against the AIDS retrovirus.

The process of drug development includes several key milestones before taking a new chemical entity into the clinic:

Preclinical – Acquisition
Screening
Lead Improvement
Evaluation
Formulation and Production
Toxicology
Investigational New Drug Application (INDA) with FDA

Clinical – Phase I Clinical Trials
Phase II Clinical Trials
Phase III Clinical Trials
New Drug Application (NDA) with FDA for marketing

Plans for NCI NIAID coordination of these various key steps in AIDS drug development are described in the following paragraphs.

First, it is important to note that this proposal is intended to streamline the development process and utilize resources efficiently. The average time for a U.S. pharmaceutical company to take a new chemical entity for the treatment of cancer from screening to NDA approval is 14 years. The average cost for a single drug to traverse the developmental milestones is $70 million.

1. Acquisition

The NCI has already screened nearly 500,000 compounds for antitumor activity. All this information is available on a computerized data base called the Drug Information System (DIS), which stores information on the preclinical data of new drugs, representing the largest data base of its kind in the world. The system is interactive and allows the retrieval of this information in seconds.

Specifically, DIS includes chemical structure, inventory supplies, physical property information, and structure-activity analysis on nearly one-half million drugs. Thus, as new lead compounds are discovered by the screening effort, precise information (including available supplies) can be immediately accessed for testing. This system will be made available to the screening effort immediately without need for additional resources.

Already, DIS has proved a potentially invaluable acquisition data base. Analogs related to nucleosides with anti-HTLV-III/LAV activity have been identified and placed into intramural screens. As predicted by structure-activity analysis, all have in vitro activity against the virus. Thus, there are lead compounds that could be immediately expedited into clinical trials.

Acquisition of other lead compounds will be expedited by the establishment of screening efforts in NIAID and National Cooperative Drug Discovery Groups by NCI, which are described elsewhere in this document.

2. Screening

The drug discovery phase of a new drug project is composed of two stages: new lead discovery and new lead development. Screening for new leads with anti-HTLV-III/LAV activity will be conducted by NIAID, predominantly utilizing the extramural contract system.

3. Drug Selection

The NIAID-NCI collaboration will cross administrative lines to ensure: (1) rapid analysis of all new data, (2) prompt decisions regarding selection of the most promising new compounds, and (3) follow up on the progress of those functions that must be completed prior to INDA filing with the FDA. This operational process will parallel the Decision Network that has been established within the NCI, but will include representatives from NIAID, NCI and the Clinical Center.

The AIDS Drug Selection Committee will evaluate screening data to prioritize those new drugs that should be expedited to formulation and production, toxicology, and Phase I trial.

4. Formulation and Production

The NCI currently has several groups of contracts in force to formulate and produce new drugs:

Off-site Quick Reaction Synthesis
Resynthesis
Preparation of Bulk Chemicals and Drugs
Production and Development of Pharmaceutical Drug Forms
Development of Dosage Forms and Delivery Systems
Storage and Distribution of Clinical Drugs

These contracts will be supplemented as necessary to provide drugs for NCI toxicology and intramural trials as well as large-scale NIAID clinical programs.

5. Toxicology

The NCI supports contracts for preclinical toxicology of new anticancer drugs. These research contracts provide toxicity data and determine end organ toxicities in these systems. These data are important in determining not only safe starting doses for clinical trials but also in providing an early indication of the likely toxic endpoints for patients on study. Equally important, these research contracts permit sophisticated preclinical pharmacology and bioavailability studies. This information is critical in determining whether achievable drug blood levels in vivo are capable of in vitro viral inhibition, whether oral formulations of a drug provide adequate bioavailability, and whether a given agent is capable of penetrating the blood-brain barrier. This latter determination is critical in view of the ability of HTLV-III/LAV to replicate in the brains of AIDS victims.

B. CLINICAL TRIALS

Phase I testing of agents identified by the screen, selected by the AIDS Drug Selection Committee, and produced and appropriately formulated by the NCI Developmental Therapeutics Program will be entered into clinical trials by the NIAID-NCI AIDS Treatment Evaluation Units. Supporting studies in clinical pharmacology will be performed by NCI to assure adequacy of drug levels, bioavailability, and distribution.

C. OTHER INITIATIVES

While the Drug Information System of NCI has already identified promising lead compounds and the NIAID screening system will likely identify others, it is important to support basic research in other potential antiviral agents at a basic level.

Promising ideas that require basic support include oligonucleotides or "anti-sense" RNA. Recently the mode of action of HTLV-III/LAV genes that leads to cell death has become clearer. A series of complex molecular switches has been described, which includes enhancers, promoters, and transactivating gene sequences. The latter are termed "rheostats," and are capable of enhancing RNA transcription at enormous speeds which may lead to cell death. Among the many possibilities offered by this knowledge is that the basic mechanism of pathogenesis can be postulated, and countermeasures could then be devised as short anti-sense messages.

Additional resources will also be utilized in several other pressing areas. Further studies will be supported in the etiology of the AIDS virus. Also, efforts will be devoted to the development of a successful animal model system. The identification of an HTLV-III/LAV-like agent as a cause of simian AIDS has been helpful in the development of a model system for either treatment or prevention of AIDS in man. The human and simian viruses are closely related immunologically and molecularly, and the disease process is remarkably similar. The finding of such an agent in normal African green monkeys, which do not get AIDS, presents an alternative primate model and allows for development of hypotheses on the origin of human AIDS.

The NCI proposes to sponsor an RFA for the establishment of National Drug Discovery Groups for the design and testing of such novel antiviral candidate compounds. This effort will be co-sponsored by NIAID.

Recent advances in molecular biology, medicinal and organic chemistry, pharmacology, and biochemistry provide unprecedented opportunities for the design of powerful antiviral therapies with unique modes of action. The complexities of these modern approaches and the urgency of the AIDS problem demand that the talents of the most creative and dedicated scientists be enlisted in concert. To accomplish this, the NCI and NIAID propose to establish a national support mechanism to permit the most outstanding scientists in viral biology, chemistry, pharmacology, and biochemistry to interact. Because few, if any, institutions possess a critical mass of all the varied talents required, National Cooperative Drug Discovery Groups for anti-HTLV-III/LAV drugs will be implemented under the Cooperative Agreement mechanism. Each group will be multi-institutional and composed of outstanding investigators from academic, nonprofit research institutions and/or industry. The NCI and NIAID will participate as members of each group, but the groups will function under the leadership of group directors from outside the Government. This interaction of academic and nonprofit research institutions with industry and Government will expedite the efficient invention of new entities and strategies for AIDS treatment as well as their subsequent development to clinical trials and marketing. The NCI and NIAID will establish several such groups, which will be supported for three years.

D. VACCINE DEVELOPMENT

The NCI has already made impressive advances in vaccine development for AIDS using isolated fractions of viral proteins from large scale HTLV III/LAV fermentation. Glycoprotein and transmembrane protein vaccines have demonstrated neutralizing activity in guinea pigs, mice, and rhesus monkeys.

Under the NIAID-NCI collaboration, NCI proposes to develop further these vaccines of viral origin and perfect their synthesis in genetically engineered systems.

NATIONAL INSTITUTE OF DENTAL RESEARCH

1986 Appropriation Estimate	$ 684,000
Sequestration	29,000
Proposed Allocation from OD	1,051,000
Total Estimate	$ 1,712,000

A. OPPORTUNISTIC INFECTIONS

The mouth of the severely compromised patient becomes colonized with noxious organisms, and, with the presence of ulcerations, the patient is at considerable risk of developing life-threatening systemic infections. Oral candidiasis is an early sign of changes in microbial colonization patterns in such patients. Recent data suggest that high-risk populations who will develop AIDS manifest oral candidiasis, while those who do not develop AIDS do not present such oral infections. Salivary glands synthesize and secrete a group of histidine-rich proteins (HRP) with potent anti-candidal activity. Accordingly, NIDR plans to support both intramural and extramural research aimed at investigating salivary antimicrobial factors, especially the HRP and sIgA, in newly diagnosed AIDS patients throughout their disease course. These studies not only will shed light on oral microbial colonization patterns in AIDS, but may also provide a prospective diagnostic tool to predict which high-risk patients will develop disease.

HTLV-III/LAV has been reported in the saliva of AIDS patients, ARC patients and seroconverted healthy homosexual controls. Basic questions on the presence and titer of the virus in gland secretions and/or whole saliva, the presence of the viral genome in parotid gland parenchyma, examination of whole saliva and gingival crevicular exudates for cells containing the virus and the status the salivary defense system (sIgA, lysozyme, lactoferrin histidine rich proteins) will be investigated.

Kaposi's sarcoma (KS) often affects the mouth in AIDS patients. In some surveys, 40 to 50 percent of AIDS cases show oral KS, and, in the absence of immunosuppressive therapy, its appearance in a male of less than 45 years is virtually pathognomonic for AIDS. Other frequent oral complications include candida and herpes simplex infections as well as carcinomas and malignant melanomas. Recently, a new form of oral leukoplakia affecting the tongue has been described within the AIDS group of diseases. The NIDR has one grant application in hand proposing studies of this new form of oral leukoplakia. The main purpose of the study is to elucidate the extent and nature of viral involvement in the lesion. The NIDR plans to encourage additional applications focusing on oral complications in AIDS patients and on their prevention, treatment, and control.

Studies on the invasiveness of Kaposi's sarcoma cells have also been initiated in an intramural research study. We have developed an assay using a reconstituted basement membrane which tests the invasiveness of tumor cells. Kaposi tumors show a considerable heterogenecity and may range from indolent to highly invasive. Based on a general survey of tumor cells currently underway, we propose testing various lines of Kaposi cells for invasiveness. We would also subculture the invasive cells to determine if they represent a more malignant cell line. Finally, various chemotherapeutic agents which interfere with cellular migration could be tested as possible adjuncts to conventional therapy.

The two most common causes of chronic pain in AIDS both relate to injury to the peripheral nervous system. Peripheral neuropathy and herpes zoster each occur in 5-10% of AIDS patients. There is little available data from controlled studies to guide analgesic treatment of patients with neuropathic pain. We have initiated studies for treatment of the chronic pain associated with AIDS patients utilizing controlled clinical trials with amitriptyline and other tricyclic antidepressant drugs.

B. INFORMATION DISSEMINATION/PUBLIC AFFAIRS

The NIDR will implement a nationwide educational program aimed at dental care providers. The program will be developed based on a survey to be conducted of practicing dentists and their auxiliaries to determine their knowledge and practices regarding: diagnosis and treatment of oral lesions associated with AIDS; prevention of transmission of infectious diseases in dental settings, and to assist practitioners who may be concerned about treating persons with AIDS. The program also will address public concerns regarding transmission of AIDS during dental treatment.

Educational efforts will include conferences, training sessions, workshops, and appropriate educational aids such as posters, leaflets films, and handbooks.

C. IMMUNOLOGIC STUDIES

NIDR investigators are focussing on the contribution of blood monocytes to the immunosuppression in AIDS. Having initially documented that monocytes are defective in AIDS patients, they are pursuing the mechanism for this disfunction. New findings, which indicate that monocytes are a target of the HTLV-III/LAV virus and of cytomegalovirus, a life-threatening infection in AIDS, give added importance and urgency to these studies. Projected investigations will be directed toward the elucidation of the HTLV-III/LAV virus-monocyte interaction at the cellular and molecular levels, as well as toward attempts to modify the monocyte dysfunction with pharmacologic agents and other immunomodulators.

NIDR investigators have also been studying the role of B lymphocytes in various immunologic disorders. Patients with AIDS exhibit profound abnormalities in their B cell function. A large proportion of normal individuals carry B lymphocytes infected with Epstein-Barr virus (EBV), which are continuously destroyed by their cytoxic T cells. However, in AIDS patients, these cells can proliferate, resulting in hypergammaglobulinemia, polyclonal hyperactivity, reduced antigen responsiveness, and the production of lymphomas. In order to understand the immunologic parameters of this disease, the NIDR plans to study: (1) the HTLV-III/LAV specific B cell frequency, (2) the frequency of spontaneously proliferating B lymphocytes; and (3) the range of antibodies secreted by the spontaneously proliferating cells. In addition, human B cell lines that secrete anti-HTLV-III/LAV specific monoclonal antibodies will be established and their use in both the diagnosis and the therapy of the disease will be studied.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

1986 Appropriation Estimate	$ 27,067,000
Sequestration	1,164,000
Proposed Allocation from OD	35,527,000
Total Estimate	$ 61,430,000

A. NATURAL HISTORY OF AIDS IN HOMOSEXUAL MEN

The NIAID is currently supporting five extramural contracts in which cohorts of homosexual men in five cities (San Francisco, Los Angeles, Chicago, Pittsburgh, and Baltimore) are being followed closely to delineate the natural history of AIDS. In addition, a contract with the New York Blood Center and Memorial Sloan-Kettering Institute is following men in New York City who participated in past hepatitis B vaccine trials or are undergoing plasmapheresis for hepatitis B antigen. For comparison, a group of homosexual men in a low-risk area (Ithaca, New York) are also included in this study. These studies will provide extremely valuable information on the transmissibility of the disease and on possible co-factors involved in the development of full-blown AIDS. Extremely important information such as the significance of HTLV-III/LAV antibody positivity and viremia as predictors of who will contract AIDS will come only from studies such as these. This type of information has important ramifications for future considerations by insurance actuaries, the military, etc.

These natural history studies were awarded for a five-year period before HTLV-III/LAV was established as the causative agent of the disease. It is now essential that these studies include testing for HTLV-III/LAV antibody and viral isolation. These tests have added substantially to the costs of the study. Not only does HTLV-III/LAV antibody testing itself cost a great deal, but concern about confidentiality of the results has made it much more difficult to recruit study participants and has added greatly to recruitment costs of the contracts. The costs for viral isolations are extraordinary. For example, a contract to perform 20 isolations per week in support of NIAID's intramural research costs approximately $500,000 per year. While the natural history contractors were given a supplement of approximately $2.5 million (to be shared by all of them) for viral isolation, this amount is not adequate for viral isolations over the life of the contracts; it is of no help with the other expenses.

Because of the recently intensified publicity about antiviral treatment and the need for accelerated development of therapies that will also draw upon a limited budget, the natural history contractors have been informed that they must operate within their originally negotiated budgets. This has required all of them either to reduce their efforts or plan termination of their contracts before the present expiration date. Specifically, studies directed at determining the importance of cofactors (i.e., hepatitis B, CMV, EBV infection) cannot be done.

It should be noted that the cost of the individual natural history contracts does not represent the total cost for this project. The NIAID intramural program supports a freezer repository in which are stored serum, lymphocytes, and other samples from participants of the studies in the five extramural contracts and the New York Blood Center contract. In addition, one NIAID intramural laboratory performs cell sorting studies (determination of lymphocyte populations) in support of the contracts and serves as a quality control standard for the studies. A program is also in effect to provide samples from these studies to academic investigators who wish to do laboratory studies with these materials. This effort requires funding of the support contract for storage and the manpower for packaging and shipping materials.

B. INTERNATIONAL EFFORTS

In addition to the natural history and epidemiology studies within this country, epidemiological studies on populations outside the United States play an important role in understanding HTLV-III/LAV infection.

The mission of NIAID supports international research and tropical medicine as components of the Institute. By participating in collaborative international efforts in AIDS research, valuable information can be obtained by researchers in the United States with regard to HTLV-III/LAV infection, transmission and co-factors, while at the same time providing information to foreign countries so that they can better protect the health of their citizens. The NIAID is currently supporting, in collaboration with the CDC, a project to study AIDS in Zaire.

In contrast to the United States, where most cases still are in homosexual males, the ratio of male to female cases in Zaire is 1:1, and there is strong evidence for heterosexual transmission. Information on the transmission of the disease in Africa may be an important indicator of the potential for a greater degree of heterosexual transmission in this country. In addition, studies of the cofactors involved in the development of AIDS in Africa may give clues to cofactors involved in the disease in this country.- It is essential that these studies be continued. In addition, studies are beginning in prostitutes in Kenya; these studies also have direct relevance to similar studies in this country. It is also now apparent that AIDS is widespread throughout the Caribbean; this has tremendous economic implications for those countries as they depend heavily on tourism and for health reasons has implications for Americans who travel extensively in this area.

The NIAID plans to initiate several important studies in addition to those currently under way in Zaire and Kenya: (1) natural history studies in homosexual populations in the Caribbean (Trinidad, Barbados, Surinam, Bahamas) and in Asia (Thailand and Singapore) through an agreement with PAHO; (2) natural history studies of heterosexually transmitted AIDS in Zaire; (3) prospective studies of AIDS in female prostitutes in Kenya, Trinidad, Jamaica, Surinam, Zambia, and Thailand; (4) studies of vertical transmission from mother to newborn, which is common in Africa; (5) studies on cofactors such as parasitic infections and their role in the development of the disease; (6) the identification of nonhuman primate reservoirs in Africa; and (7) studies of racial/genetic factors that may influence acquisition of infection and expressions of disease; e.g., there is an unexplained difference in the rate of disease in those of African versus Asian descent in Trinidad.

C. DEVELOPMENT AND TESTING OF DRUGS FOR THE TREATMENT OF AIDS AND OPPORTUNISTIC INFECTIONS

Major efforts are currently under way in the intramural clinical facilities of the NIAID and NCI to evaluate antiviral agents and immune reconstitution in AIDS and AIDS-related-complex patients. Investigators in the NIAID and the NCI are studying the use of suramin as an antiviral agent, and NCI investigstors have a modest program to screen for new antivirals and evaluate other candidate antivirals developed by industry. In addition, NIAID investigators are studying a number of immunomodulators such as interleukin-2 and are attempting procedures such as bone marrow transplantation in an attempt to reconstitute the immune system. Studies are also under way to evaluate drugs for the treatment of the opportunistic infections to which most AIDS patients succumb. Extramurally, increased funding will be used to fully support ongoing studies on suramin as an antiviral agent in AIDS patients.

In addition to these research efforts, the NIAID and the NCI have developed a collaborative plan for the development and testing of drugs for the treatment of the AIDS retrovirus as well as the concomitant opportunistic infections:

1. Screening for New Antiviral Drugs

Increased funding in 1986 will support NIAID sponsored contracts to screen antivirals in 1986, as well as provide for the co-sponsoring of an NCI RFA for the establishment of the National Cooperative Drug Discovery Group for the design and testing of novel anti-HTLV-III/LAV candidate compounds.

2. Selection of Drugs for Clinical Trials

This will be done by a joint NCI-NIAID committee.

3. Preclinical Toxicology, Formulation, and Pharmacology

This will be done under existing NCI toxicology contracts within NCI's Developmental Therapeutics Program.

4. Investigational New Drug (IND) Preparation and Submission to FDA Staff

This will be directed by NIAID and NCI staff with experience in this area.

5. Clinical Trials

A comprehensive plan for the further development and evaluation of drugs for the treatment of HTLV-III/LAV infection, immune enhancement and treatment of opportunistic infections has been identified by NIAID. The Institute currently supports a number of extramural projects through the contract mechanism for the development and evaluation of drugs for the opportunistic infections in persons with AIDS. These projects will be maintained in the extramural AIDS Program.

In addition, the NIAID AIDS Program has advertised an RFP for the establishment of 10 AIDS Treatment Evaluation Units. The program is a collaborative effort between NIAID and NCI although the total funding requirements associated therewith are reflected in the NIAID submission alone. These units, operated analogously to the NIAID vaccine evaluation units, will provide a mechanism to support large scale Phase I and II clinical trials. In this setting, candidate antiviral drugs, immune enhancement agents and treatment for opportunistic infections will be evaluated in HTLV-III/LAV infection.

D. AIDS VACCINE DEVELOPMENT AND TESTING

The NCI is pursuing the development of an HTLV-III/LAV vaccine using techniques to break up the whole virus and dissect those antigens that may prove useful as immunizing agents. Preparations using this approach are now in the stage of animal testing. The NIAID, as well as the NCI, is also pursuing the development of vaccines using recombinant DNA and monoclonal antibody technology. While this approach is still in the laboratory stage, it is possible that candidate vaccine preparations could become available for animal and eventually human testing within the next several years. The NCI has developed an RFA for grants to develop retroviral vaccines, and the NIAID will co-sponsor this effort.

E. AIDS OUTREACH ACTIVITIES

Advances in AIDS research must, of course, be transmitted to the public. The NIAID supports an AIDS outreach program that has held a series of conferences throughout the United States aimed primarily at health care professionals and public service personnel. These conferences have been very successful and in all cases have been over subscribed.

The NIAID plans the continuation of these types of outreach activities and the development of new ones. For example, packaged workshops on AIDS should be developed and made available for presentation at local and national professional and lay meetings. A recent workshop on AIDS presented by NIAID staff members and grantees was part of the program for the national meeting of the National Medical Association, and it was very well attended. Specialized conferences and workshops designed to bring the latest information on the treatment of AIDS patiants will be presented in major metropolitan areas where there are large numbers of AIDS cases. These will be designed for physicians who are caring for the patients. These and other programs, perhaps through cooperation with organizations such as the Hospital Satellite Network, could be televised for distribution and viewing around the country.

OFFICE OF THE DIRECTOR, NIH

Amount to be held in Reserve	$ 3,041,000

The NIH believes that it is essential to maintain some flexibility to pursue new leads and findings in 1986 and plans to hold $3 million in reserve for this purpose. The use of this fund will depend principally on the opportunities to respond to and exploit research progress and discoveries, although some proposals now in hand will also be considered for funding under this reserve. Progress will be monitored by the NIH AIDS Executive Committee, and their recommendations will guide the use of this reserve, which will be obligated before the end of the fiscal year. Vaccine development and testing is considered to be a high priority area for the potential use of these funds.

ADDITIONAL APPROVED PROJECTS

Among the areas that have been approved at the NIH, but will not be funded under the 1986 revised budget, are the following:

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

A. DEVELOPMENT OF NEW BLOOD TESTS

Continued evaluation of serum obtained from a large spectrum of individuals exposed to HTLV-III/LAV and those with clinical symptoms has strongly emphasized that research aimed at the development of serological assays for the detection of antibody and antigen is, at best, at an infancy level. Several goals must be accomplished in the future, so that all units of blood and/or blood products can be certified to be free of this infectious agent. For example, the sensitivity and specificity of current assays for antibodies to HTLV-III/LAV needs to be improved. The fact that infectious virus may be present at quantities below the sensitivity level of the present methods indicates that a major research effort should be initiated in this area. Methods to detect integrated virus are needed in order to adequately assess infectivity of transfused or transplanted materials or potential susceptibility of recipients.

B. EVALUATION OF CURRENT BLOOD TESTS

Current blood tests need to be continually evaluated for effectiveness. The Institute would follow heavily transfused patients without HTLV-III/LAV antibody who are given screened blood to determine the effectiveness of screening tests and practices.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

A. PREVENTION OF AIDS TRANSMISSION

Barrier contraception may prevent the transmission of HTLV-III/LAV within high-risk AIDS populations. The efficacy of various combinations of barrier contraceptives to reduce the risk of AIDS should be evaluated so that firm contraceptive-use recommendations can be made for current high-risk populations. Current recommendations are that high-risk individuals use condoms during intercourse to reduce their risk of developing AIDS. This recommendation is based on confirmation that body fluids carry HTLV-III/LAV and on the assumption that condoms, proved highly effective for vaginal birth control, must be reliable barriers. But it is not known whether condoms can be penetrated by HTLV-III/LAV, and it has not been established that condoms represent reliable barriers for any sexual activity other than vaginal intercourse.

Given the virulence of HTLV-III/LAV and pending further data on the suitability of the condom alone as an effective physical barrier to sexually transmitted diseases, the Institute would initiate efforts to evaluate the role of maximum barrier contraception.

B. EPIDEMIOLOGY STUDIES

Surveillance for a possible introduction of newly discovered retroviruses into the U.S. population may be facilitated by monitoring the health of women with multiple sexual partners. Several surveys completed or currently under way document the rapidly rising prevalence of HTLV-III/LAV among well established high-risk populations, such as homosexuals and IV drug users. Less is known about the seroprevalence of HTLV-III/LAV in prostitutes, but it is feared that this group may serve as the most efficient conduit for HTLV-III/LAV transmission to sexually active heterosexual males. Recent evidence of a 5 percent seropositivity rate among U.S. Army troops in Germany has reinforced this concern since exposure to prostitutes far exceeds drug use.

In collaboration with the NCI, the Institute would initiate a follow-up study and seroanalysis of past and future blood specimens. All sera would be sent for both screening and confirmation at a commercial laboratory routinely performing ELISA antibody tests. Reactive specimens would be sent to a separate contractor in the Washington area for Western blotting.

DIVISION OF RESEARCH RESOURCES

A. NATIONAL CHIMPANZEE MANAGEMENT PLAN

Because of its close similarity to man, the chimpanzee is very important as a research animal. It is an irreplaceable human surrogate for such areas of research as communicable diseases, vaccine development and testing, neurosciences, learning, and behavior. Continued predation and habitat destruction in countries where the chimpanzee is native have resulted in a precipitously declining population. Accordingly, many countries, including the United States, have enacted legislation to protect the chimpanzee. Wild populations of chimpanzees can no longer be drawn upon to meet either domestic breeding or research needs. In fact, chimpanzees have not been imported into the United States for biomedical research from African countries of origin since 1973. While there are about 1,600 chimpanzees presently in the United States (1,200 of these are associated with use in biomedical research and testing programs), the number of these animals that are behaviorally and physically suitable for breeding purposes numbers less than 400 animals and that number is declining each year. Demographic studies suggest that there will not be sufficient numbers of suitable chimpanzees available in the United States beyond the year 1987 to assure the establishment of a self-propagating population.

Given the high priority attached to the development of vaccines to prevent AIDS, the need for chimpanzees as the only current suitable animal model for the testing of candidate vaccines, and the worldwide scarcity of chimpanzees, the NIH is considering the implementation of the National Chimpanzee Management Plan.

VACCINE DEVELOPMENT

Increased support would be provided for the co-sponsored NIAID/NCI Request for Applications to encourage investigator-initiated research on retroviral vaccines in various laboratories which specifically emphasize basic studies on the development and assessment of retroviral vaccines. Key areas may include: development of animal models to systematically evaluate strategies for immunogen preparation, vaccination schedules, use of suitable adjuvants, induction of a protective immune response, and development of an appropriate measure for in vivo protection against challenge; and utilization of newer methodologies to produce and evaluate vaccines such as: (a) recombinant/subunit vaccines prepared in yeast, bacteria, and/or mammalian cells, and (b) DNA sequence derived synthetic peptides, etc. Confirmatory studies will be undertaken in higher primates before clinical trials are implemented in AIDS patients by NIAID through existing NIAID vaccine evaluation units.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Alcohol, Drug Abuse, and Mental Health Administration

REPORT ON ALCOHOLISM TREATMENT

Robert L. Trachtenberg
Acting Administrator, ADAMHA

February 1986

INTRODUCTION

This report is submitted to the House and Senate Appropriations Subcommittees on Labor, Health and Human Services, and Other Related Agencies in response to requests for information on treatment research, particularly in the area of patient placement, and on the programs and plans of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) in this area.

Relevant topics covered in this report are current trends in the treatment system; recent achievements in treatment research, including advances in assessment technology, new approaches to patient placement, and NIAAA research on third-party coverage of alcoholism treatment; discussion of ongoing treatment research programs; research opportunities; and new NIAAA initiatives in fostering patient placement research.

TRENDS IN THE TREATMENT SYSTEM

Dramatic changes in the alcoholism treatment system have occurred in the United States over the past decade. These include changes in reimbursement policy for alcoholism treatment, expansion of inpatient treatment, growth of Alcoholics Anonymous, and the emergence of nontraditional sources of recruitment into treatment (e.g., Employee Assistance Programs, drinking driver programs).

Between 1978 and 1983 there was a 58 percent increase in the number of hospital inpatient units treating alcohol and other drug dependency patients, as reported by the American Hospital Association. A major redistribution also occurred in the share of hospital inpatient treatment beds held by the three ownership categories. For-profit institutions showed the greatest proportionate growth, from 5 percent to 16 percent, probably in response to changes in insurance reimbursement. The share of patients treated by nongovernmental, nonprofit institutions increased from 31 percent to 41 percent. The number of units affiliated with State, local, and Federal governments declined from 64 percent to 43 percent. The 23,000 inpatient hospital beds in 1983 are supplemented in the treatment system by a nearly equal number of inpatient beds in other alcoholism treatment settings such as freestanding rehabilitation and other residential and halfway house programs.

In addition to this redistribution of ownership of hospital inpatient beds, there has been a significant expansion of other parts of the treatment system. Of the estimated 290,000 patients registered either as inpatients on September 30, 1982, or as outpatients during the month of September 1982, 18 percent were in 24-hour care program facilities. The majority, 72 percent, were being treated on an outpatient basis.

A number of other trends are evident. Early counseling or referral to specialized treatment is becoming increasingly prevalent in employment settings and health maintenance organizations. Both inpatient and outpatient programs are targeting their services at special population groups such as the military, adolescents, children of alcoholics, employee groups, professionals, women, homosexuals, and drunk drivers. Program utilization is being promoted by media advertising in many parts of the country.

Despite great increases in the availability and scope of alcoholism treatment services, however, there has been a trend toward homogeneity in therapeutic approaches around an inpatient rehabilitation model consisting of detoxification, alcohol education, group confrontational therapy, and Alcoholics Anonymous meetings.

This broad range of alcoholism services, offering a continuum from detoxification to aftercare, makes research on the relative efficacy of different therapeutic modalities and treatment both practical and imperative. There is a great need to increase cost-effectiveness by learning how to assign individuals to the most therapeutically appropriate and least expensive treatment.

RECENT ACHIEVEMENTS IN TREATMENT RESEARCH

Some notable achievements in treatment research have occurred in recent years, in patient assessment techniques, new approaches to placement, and third-party treatment coverage.

Advances in Assessment Technology

Advances in the technology of assessment have led to the development of new techniques for screening and diagnosis. The combined use of biochemical tests, clinical examinations, and questionnaires on alcohol consumption now make it feasible to identify large numbers of problem drinkers who could benefit from early intervention, especially when these screening methods are used in conjunction with behavioral indicators such as alcohol-related accidents, impaired job performance, and drunk driving.

Paralleling these developments has been a rapid improvement in the technology of differential assessment, that is, procedures to diagnose and measure alcohol dependence as well as its related physical, mental, and social disabilities. This has made it possible to obtain a comprehensive description of the full spectrum of alcohol-related disabilities that must be taken into account in any systematic plan for placing alcoholic patients.

Working groups sponsored by the NIAAA, the American Psychiatric Association, and the World Health Organization have been meeting during the past 3 years for the purpose of improving diagnostic procedures and are in the process of developing new diagnostic instruments capable of confirming diagnosis of alcohol dependence reliably and quickly.

New Approaches to Patient Placement

Some notable advances in basic research have begun to stimulate new approaches to the treatment and the placement of patients. Neuroendocrine (insulin) and psychophysiological (skin conductance) variables have been identified as correlates of craving in laboratory settings. These findings have helped to clarify the potential importance of biological and physiological responses in the development of alcohol dependence. Research underway on procedures to measure the severity of alcohol dependence may soon make it possible to assign patients to different types and intensities of treatment, based on their vulnerability to readdiction.

Psychological Investigations. The investigation of psychological expectancies, such as beliefs about the disinhibiting effects of alcohol, has shed new light on the complex mechanisms underlying the disruptive effects of alcohol on the behavior of individuals, particularly those who believe that alcohol makes them act inappropriate. These findings may lead to the development of more appropriate treatment interventions designed to prevent the recurrence of violence and other types of alcohol-related deviance often observed in treated alcoholics.

The application of psychological learning theory has led to specific treatment techniques designed to prevent relapse into alcoholism and minimize the effects of brief lapses from abstinence. A scientific basis for these new approaches has been provided by studies of alcoholics' strategies for coping with stressful life events and high-risk situations during the crucial transitional period that occurs after treatment is completed.

Early Intervention Studies. The potential of basic research to benefit clinical practice is also indicated by several recently completed early intervention trials with nondependent or less dependent problem drinkers. Using newly developed screening techniques, for example, liver enzyme tests, and brief counseling procedures, investigators in Sweden and Scotland have shown that early intervention can prevent alcohol-related problems and reduce demand for more costly health services.

Research on Alcoholic Subtypes. The study of subtypes of alcoholism, one of the most promising areas of research, has benefitted greatly from newly developed assessment technologies such as the NIMH Diagnostic Interview Schedule. Available evidence suggests that psychopathology and a family history of alcoholism are associated with poor prognosis, and that more intensive treatment for these types of patients therefore may be warranted. Other data indicate that married socially stable patients who develop alcoholism later in life respond better to treatment. This type of patient may be a good candidate for less intensive treatment.

Treatment Evaluation Research. Advances in methods to evaluate treatment processes, such as the amount of information gained during alcohol education classes, may eventually lead to more accurate estimates of the relative contributions of client characteristics, therapeutic interventions, program settings, and environmental variables to the success or failure of treatment. They may also help generate new research findings about the overall efficacy of alcoholism treatment as well the relative cost-effectiveness of different intensities and types of treatment.

NIAAA Research on Third-Party Treatment Coverage

The NIAAA has conducted many studies to help the Federal, State, and local governments, the health insurance industry, and the alcoholism field develop informed policy on coverage for alcoholism treatment.

One NIAAA-sponsored study examined health insurance claims of the Aetna Federal Employees Health Benefit Program (FEHBP) enrollees, covering a 4-year period, and found that alcoholism treatment can be cost effective. The data showed a gradual increase in health care utilization and cost for alcoholics during the 3 years preceding alcoholism treatment with the most dramatic rise occurring in the 6 months prior to admission to alcoholism treatment. After initiation of alcoholism treatment, general health care costs dropped significantly and reached pretreatment levels. The study estimated that the average cost of alcoholism treatment under the Aetna FEHBP could be offset by reduced health care costs within 2 to 3 years following the initiation of treatment.

Similarly, an NIAAA-sponsored study of 50 families with an alcoholic member who were enrolled with Blue Cross and Blue Shield of Northern California found that total medical care costs per family member, both inpatient and outpatient, decreased substantially over time after the alcoholic family member was admitted to an alcoholism treatment program. By the end of the study, inpatient costs per person per month in the alcoholic families were similar to those of a comparison group of families -- and outpatient costs were actually lower.

Other such studies funded by the NIAAA include:

o A demonstration in collaboration with the Health Care Financing Administration of lower cost alternatives for alcoholism care in Medicare and Medicaid programs;

o A study of the costs and utilization of health care for alcoholic employees of a large self-insured corporation and their family members following treatment for alcoholism;

o A demonstration with the Blue Cross/Blue Shield Association to test the feasibility of broad-based coverage for alcoholism treatment in the Blue Cross system;

o A study to demonstrate that services for alcoholism and related health problems can be an accepted and routine part of care provided by a health maintenance organization.

These studies vary in scope, methodology, and study populations, but in the aggregate they offer increasingly persuasive evidence that alcoholics and their families initially use more health care services than nonalcoholics, that this elevated demand declines substantially after treatment for alcoholism, and that the benefits of alcoholism treatment outweigh its costs.

ONGOING TREATMENT RESEARCH

A major study of early intervention strategies is being conducted in 11 countries, including the United States, as part of an international collaborative study. Collaborating groups funded by the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), the World Health Organization, and the American Psychiatric Association are participating in a major revision of standard diagnostic procedures used for treatment placement and epidemiological surveys of alcoholism prevalence. Researchers have initiated several large-scale studies to identify distinct subgroups of alcoholics who might benefit from specific types of individualized treatment. Scientists at one of the NIAAA's nine Alcohol Research Centers are studying a variety of questions related to alcoholism treatment, including screening and differential diagnosis, matching patients to different aftercare modalities, and the effect of genetic and psychiatric history on treatment response. Investigators in the field of treatment research are seeking ways to apply new basic and clinical knowledge about alcoholism. For example:

- o New knowledge of the genetic basis of alcoholism has stimulated research on treating the children of alcoholics.
- o New knowledge of the neurological deficits resulting from chronic drinking has stimulated research on the role of cognitive recovery in a patient's response to inpatient treatment.
- o New knowledge of the etiology of alcohol-related psychiatric illness has stimulated research interest in the joint treatment of depression and alcoholism.

RESEARCH OPPORTUNITIES

Advances in the scientific understanding of alcoholic drinking behavior may have important implications for treatment methods. Refinements in diagnostic criteria and in the measurement of alcohol dependence point to the dependence syndrome concept as a crucial area for future research. Severity of dependence may be an important criterion for matching patients to intensity of treatment. Research on the biological, cognitive, and behavioral mechanisms of dependence should prove extremely useful for both diagnosis and treatment planning. On a more general level it seems important to investigate the influence of other patient characteristics, such as sex, marital status, social support, ethnic background, and socioeconomic status, since these factors are often the *de facto* basis for referring alcoholics to different types of treatment programs.

Other areas of basic research likely to lead to advances in treatment are:

1. Investigations of alcoholics' cognitive expectancies and how they affect the initiation and course of relapse;
2. The role of high-risk situations and environmental stress in the precipitation of relapse;
3. The therapeutic role of family and other social support systems during the crucial period following treatment;
4. The contribution of genetic and familial influences to the more severe course of alcoholism observed among alcoholic children of alcoholics;
5. The contribution of antisocial personality characteristics to the violent behavior often observed in alcoholics;
6. The development of brief screening tests capable of identifying heavy drinkers and other persons at risk of alcoholism.

The most pressing research questions concerning treatment have to do with the placement of patients: the relative efficacy of different therapies, the appropriateness of inpatient vs. outpatient program settings for different types of patients, the optimal length of stay in inpatient facilities, and the ideal mix of services ranging from detoxification to aftercare.

An emphasis on applied research will be needed to resolve these questions and develop a suitable base for policy decisions. For example, before large-scale research on patient placement can begin, it is necessary to develop a differential assessment battery capable of measuring relevant patient characteristics and treatment variables. To be useful for treatment planning, the information must be collected and scored quickly. Advances in computer-assisted test administration make this mechanism ideal for feedback to clinicians, placement of patients, and treatment evaluation.

Applied research is also needed to develop "process" measures capable of evaluating the short-term impact of various treatment components, for example, changes in attitudes, motivation, knowledge, and skills resulting directly from exposure to particular components of a treatment program. Research on the process of treatment, as well as on overall treatment outcome, could provide valuable information as to which components of multimodal programs are useful and which are superfluous. Finally, better technology is needed to monitor compliance with various treatment regimens.

There is general agreement in the field that the NIAAA's research agenda should consider a new generation of efficacy and cost-effectiveness studies that take into account the relative contributions of client characteristics, program variables, therapy modalities, and treatment intensity. Previous multicenter outcome monitoring studies such as those conducted in 17 New York State Alcoholism Rehabilitation Units (Welte et al. 1979), 44 NIAAA-supported facilities (Armor et al. 1981), and 4 health maintenance organizations (Plotnick et al. 1982) demonstrate the feasibility and productivity of large-scale monitoring studies of treatment outcome among different clients and settings. The field will be ready for more sophisticated monitoring studies once the required improvements in assessment technology, conceptualization, and methodology have been achieved. In addition to these descriptive or monitoring studies, controlled clinical trials should also be considered. The concept of controlled clinical trials, first introduced to medicine in the 1930s, has led to significant advances in the treatment of syphilis, diabetes, pneumonia, and cancer. These studies require that patients be assigned randomly to specific kinds of treatment rather than merely describing treatment outcome after the natural referral process. Although large-scale controlled trials are well established for drug therapies, they are less well established for surgical procedures and psychotherapy. Controlled clinical trials clearly provide a more rigorous scientific basis to evaluate the efficacy of systematic patient placement. Experience with a recent trial of clinical approaches to the prevention of coronary heart disease, however, indicates a need for caution in the use of this procedure in situations where treatment modalities are complex, patient populations are difficult to define, and outcome measures are difficult to assess (Multiple Risk Factor Intervention Trial Research Group 1982).

While these caveats apply to alcoholism treatment, they do not preclude consideration of small-scale clinical trials for more circumscribed types of treatment questions, for example, social skills training versus group psychotherapy in the outpatient treatment of nondependent or less dependent problem drinkers.

Innovative treatments, such as the community reinforcement approach, aversion methods, social skills training, behavioral self-control training, family therapy, and certain pharmacologic interventions, need to be studied more systematically, especially in relation to more traditional approaches including Alcoholics Anonymous, disulfiram therapy, group therapy, and alcohol education.

To answer more pressing policy questions it may be appropriate to initiate one or two large-scale monitoring studies of complex treatment systems. The various dimensions of these systems, such as program settings (hospital-based vs. freestanding), program types (outpatient vs. inpatient), method of treatment (Alcoholics Anonymous vs. behavior therapy), and intensity of treatment (short-term vs. long-term), could be studied in relation to a broad range of client characteristics or patient types. The intensive investigation of large numbers of patients in monitoring studies as they proceed through various components of the alcoholism treatment system would yield valuable descriptive information on the relative efficacy and cost-effectiveness of naturally occurring variations in length of stay, type of program, and method of treatment.

The advantage of combining small-scale clinical trials with large-scale outcome monitoring studies is that complementary types of data will be generated to guide planning and policy decisions.

NEW NIAAA INITIATIVES IN PATIENT PLACEMENT RESEARCH

The National Institute on Alcohol Abuse and Alcoholism is expanding its support of research in the area of matching clients to treatment. The Institute's plans for research that will lead to the development of a comprehensive patient placement system include a regular research grant program as well as a new exploratory research project grant program on treatment.

The research grant program has been inaugurated by the issuance of an in-depth, highly focused grant program announcement on the topic of matching clients to treatments, an issue central to research which will lead to the development of a comprehensive patient placement system. It is anticipated that this announcement will encourage and facilitate early submission of the high-quality proposals needed in this complex research area. Proposals received in response to this announcement, which is being disseminated widely, are expected to be reviewed in fiscal years 1986 and 1987.

The purpose of the exploratory research project program is to support planning, organization, and development of new treatment research projects that will examine patient matching in alcoholism treatment. These feasibility studies may explore various approaches to the development of projects that offer potential solutions to problems surrounding placement of patients in appropriate treatment programs. The program is intended to supplement the existing research grant program on treatment. The existing program needs to be supplemented with exploratory studies because of the complexities of this type of research. The exploratory program will be developed by a four-step process that includes development of concept papers with the advice of outside experts, solicitation of proposals, rigorous peer review of those proposals, and awarding of grants. By using this four-step process we hope to stimulate high-quality research grant applications as well as increase the diversity of research in this area.

Additional encouragement of research in this area is being provided by recently published NIAAA documents relevant to the conduct of treatment assessment research. An important example is the document, Classification of Alcoholism Treatment Settings. Two other titles of related interest are State Resources and Services for Alcohol and Drug Abuse Problems and Resource Directory of National Alcohol-Related Associations, Agencies, and Organizations.

In addition to these specific activities, NIAAA has participated in several cross-cutting initiatives to assess financing and coverage policy issues as they affect the alcohol, drug, and mental health fields. Due to the fact that abuse of both alcohol and drugs, often in combination with other mental health problems, is becoming increasingly prevalent, the Administrator of ADAMHA has created a task force with senior representatives from each of the three Institutes (NIAAA, NIDA, and NIMH) and charged them with developing an agency-wide reimbursement and coverage policy agenda.

CONCLUSION

The most pressing research questions concerning alcoholism treatment have to do with the placement of patients. The NIAAA agrees with the House and Senate Subcommittees that research on ways to match intensity of treatment services with the severity of disability (patient placement research) is a matter of high priority in the alcoholism field. General progress in alcoholism treatment research is at a point where such investigations appear feasible and likely to be productive. The Institute's new exploratory research project grant and research grant initiatives create a framework that will bring real progress in our ability to match clients with the most appropriate treatments.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

National Institute on Aging

RESEARCH ON ALZHEIMER DISEASE

Thomas E. Malone, Ph.D.
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February 1986

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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RESEARCH ON ALZHEIMER DISEASE

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Research on Alzheimer Disease

Executive Summary

In its FY 1986 report, the House Committee on Appropriations of Labor, Health and Human Services, and Education and related agencies made a request for information on the National Institute on Aging's initiatives on family stress problems relating to the care of older persons with Alzheimer Disease (AD) and the development of family care and service delivery models.

In response to this request this report will discuss what is currently known in this area, present brief descriptions of recently funded grants, and indicate future research needs and methods for disseminating new knowledge.

Some important behavioral sciences research on AD is already being funded by the National Institute on Aging. Five major research topics were identified as needing additional research. These include:

1) the availability of family members to care for AD patients;
2) caregivers' perception of and response to AD symptoms;
3) the influence of familial factors on the onset and/or exacerbation of AD symptoms;
4) the burden of AD on caregivers;
5) the use of informal and formal resources.

The burden of AD on patients, informal caregivers and the health care system is enormous. Identification of the range of informal and formal services is especially important for understanding how to balance familial and professional support in a cost-effective and humane way.

RESEARCH ON ALZHEIMER DISEASE

INTRODUCTION

In its FY 1986 report, the House Committee on Appropriations for Labor, Health and Human Services, and Education and Related Agencies made a request for information on the National Institute on Aging's initiatives on family stress problems relating to the care of older persons with Alzheimer Disease (AD) and the development of family care and service delivery models. The Committee's request is stated as follows:

> The Committee notes that the Institute has initiated a program focusing on the family stress problems relating to the care of victims of Alzheimer Disease and the development of family care and service delivery models. The Committee expects that these initiatives will be continued in FY 1986 and the Institute will submit a report on these initiatives (page 73).

In response to this request this report will discuss what is currently known in this area, present brief descriptions of recently funded grants, and indicate future research needs and methods for disseminating new knowledge.

The National Institute on Aging (NIA) is concerned with furthering knowledge on multiple aspects of Alzheimer disease. Our efforts in this area include studies of family stress problems relating to the care of Alzheimer victims and the development of family care and service delivery models.

Research is just beginning to focus systematically on how families and other social supports affect and are affected by Alzheimer disease (AD) and related disorders. Additional studies are needed on the social and psychological aspects of AD to help advise family members and professionals who are currently caring for older persons with AD. Identification of the range of informal and formal services is especially important for understanding how to balance familial and professional support in a cost-effective and humane way.

Recently a task force was convened by the Secretary of the Department of Health and Human Services with the National Institute on Aging as the lead agency to review current status and future directions for research on families, informal supports and AD. This group identified five major topics for study:

- o the availability of family members to care for AD patients;
- o caregivers' perception of and response to AD symptoms;
- o the influence of familial factors on the onset and/or exacerbation of AD symptoms;
- o the burden of AD on caregivers;
- o the use of informal and formal resources.

Research highlights from each of these areas will be reviewed briefly in this report.

BACKGROUND

o The majority of persons with AD live at home and receive care from a relative or friend. Family members are shown in study after study to be the primary caregivers of the elderly patients. However, few studies have systematically documented actual caregiving behaviors, with large numbers of AD patients, with varying levels of impairment representing the full spectrum of the disease. We need to know who is giving what kind of care to what types of patients with what results. We also need to know how changing social and demographic trends (such as the increasing participation of women in the paid work force) will affect informal caregivers' availability and willingness to care for AD patients in the future.

o The role of families and informal caregivers in the perception of and response to AD symptoms is another area that merits investigation in greater detail. Beliefs about the causes and treatments of a particular illness have been shown to affect whether - and in what ways - the family responds to illness symptoms. Little is known about how families and other informal caregivers seek professional advice and treatment. Such research should include studies of familial, psychosocial, or environmental factors that are associated with the early recognition of AD symptoms, with denial of serious symptoms, with the decision to seek professional advice and treatment, and the different approaches to management at home.

o Relevant to AD, substantial literature is being accumulated on the role that the family and other informal supports play in the onset, course, and outcome of a variety of chronic diseases and disabilities. There is some evidence that familial attitudes, behaviors, and interactions can either aggravate or lessen the occurrence of the cognitive and behavioral deficits associated with AD. Research is needed to explore how social and behavioral factors, interacting with biological processes, affect the onset and/or exacerbation of symptoms associated with AD.

o Families and informal caregivers of persons with dementing disorders experience a variety of physical, psychological, social, and financial difficulties. More research is needed on the antecedents and consequences of these different types of burdens. Characteristics of both the caregiver and the patient, as well as the caregiver context, need to be further delineated. We need to know, for example, how family members of different ages, sexes, socioeconomic and cultural backgrounds, or levels of responsibility are affected by having a relative with AD. We also need to know what factors contribute to stress and why families reach a breaking point.

o There are several key family resources for helping AD patients remain at home, including: 1) competent health care; 2) Alzheimer support groups and; 3) respite care. Additional research may find ways to help informal caregivers understand and cope with the symptoms of AD and the burdens of caregiving. Little attention has been given to the ways in which families use - or fail to use - both informal and formal support services to care for AD patients. Further research is needed on ways to assist those who are trying to care for AD patients at home.

The use of formal supports does not consistently reduce the burdens on caregivers. Carefully planned clinical trials are needed to evaluate the effectiveness of different types of health and social services. Additional research is also needed on how families, health professionals, and AD patients relate to each other, particularly in institutional settings. Contrary to popular stereotypes, families do not typically abandon older relatives who have been institutionalized but continue to be involved.

ACCOMPLISHMENTS

The current knowledge about families, informal supports, and AD has increased in the past few years. The following are brief descriptions of research projects that illustrate the types of studies NIA is currently funding:

A multidisciplinary study by Dr. Asuman Kiyak at the University of Washington, Seattle, is examining the adaptive process of elderly persons with diagnosed AD. Fifty AD patients still living in their own homes are being compared with fifty healthy older persons with similar backgrounds. This study is addressing problems arising from the AD victims' progressive inability to meet the environmental demands of daily living as their disease worsens. The research team, which involves clinicians, behavioral scientists, and architects, is examining whether stresses resulting from an increasing mismatch between personal capabilities and environmental demands can be reduced by modifying either the social or physical environment. Recommendations for the management and enhancement of well-being among dementia patients and their families should emerge from this study.

Two new research projects on AD patients and their caregivers have recently been funded. The first study by Dr. Richard Schulz at the University of Pittsburgh, will examine how people cope as the disease progresses. Approximately 200 initially mild to moderate dementia victims and their caregivers will be followed for a period of two-and-one-half years. This study represents one of the first attempts to investigate the full range of factors thought to account for long-term coping among caregivers of dementia victims. This study should help in the design of more appropriate and cost-effective services for caregivers which may, in turn, help to postpone costly institutional care placements.

A second study by Dr. David Chiriboga at the University of California-Davis, will examine the stresses and strains imposed by the presence of a parent with AD, the effect of these stresses and strains upon family process, and how adult children and their parents attempt to resolve the problems. These investigators will explore how children respond to their parents' needs for aid and support. The findings from this study should contribute to basic understanding of the way in which family members attempt to help each other under conditions of chronic strain. Like the other two studies, this research should also be useful in developing intervention programs for helping family members care for AD patients at home.

In addition to studies focused directly on families and AD, NIA is funding several other studies which are contributing to our general knowledge of informal caregiving provided to frail elders living at home. For example, using a large community sample, Dr. John McKinlay of Boston University is documenting: who is providing care to frail elderly, the types and amounts of care provided, and the burden on family caretakers of chronic illness and disability. This study will attempt to discover why some family members provide extensive care while others do not. Contrary to previous assumptions that caregiving falls predominantly on women, some men are also heavily involved in caregiving activities.

Several other NIA studies are concerned with the development and evaluation of innovative ways to reduce caregiver stress and burden. For example, Dr. Delores Gallagher of the VA Medical Center in Palo Alto is testing different strategies for enhancing the capacity of relatives to care for frail elders.

The NIA is also concerned with how older people relate to formal health care services. This will be increasingly important in our understanding and prediction of health care use among AD patients and their families. NIA is supporting projects in this general area, including research on factors explaining who is likely to use health care; how the structure and organization of health care services affect patients and their families; how health care professionals and patients relate to each other and how these interactions affect patient health and functioning; and special issues of daily living and care in nursing homes. Of direct relevance to NIA's Alzheimer initiative is a new Small Business Innovative Research grant to develop a prototype for overnight respite care for frail older adults. In phase 1, the project will establish preliminary data on the client referral market and on the ability to obtain and train foster care providers.

DISSEMINATION OF NEW KNOWLEDGE

There are several ways in which new knowledge can be disseminated and translated into practice. New information needs to be disseminated at two levels: 1) the professional/scientific community, and 2) lay persons and community groups. The first can be accomplished through investigators publishing in the scientific literature and through scientific conferences and workshops whose purpose is to integrate and summarize existing research findings. Educational and programmatic implications of this research should be identified and implemented.

At the second level, the NIA's Public Information Office has been very successful in disseminating key research findings to the public. For example, Age Pages which are written for the public reach millions of lay persons. Moreover, the Institute has been working closely with the Alzheimer Disease and Related Disorders Association to translate the latest scientific information for consumption by both practitioners and lay persons.

Easily understandable material on the medical aspects of AD is now available for dissemination to Alzheimer Disease support groups or to individuals upon request. A current report on the state of research on families and AD was part of the Secretary's Task Force Report on Alzheimer Disease released in 1984. It is anticipated that updated information on family care and service delivery options will be developed and available for public and professional use as significant findings become available.

CONCLUSION

The burden of Alzheimer Disease on patients, informal caregivers, and the health care system is enormous. Systematic research is just beginning to focus on how families and other social supports affect and are affected by AD and related disorders. The NIA plans to encourage more research in this area as part of its ongoing initiative on Alzheimer disease. As the results of research become available, NIA will continue to disseminate information to the professional community and the lay public. The results of ongoing research should contribute to the development and testing of innovative health care models for helping to reduce the tremendous burdens associated with caring for AD patients in the home.

AoA Report on Current Alzheimer's Disease Activities

A) Support Services Demonstration Projects

The Administration on Aging recently made twelve (12) new grant awards to projects designed to find more effective ways of serving Alzheimer's Disease victims and their families. The new grantees were successful in a competition among a total of 88 applicants under one category of the FY 1985 Coordinated Discretionary Funds Program.

Alzheimer's Disease, the major form of dementia among older persons, has catastrophic emotional and financial consequences. The families of the victims face increasing demands and decreasing resources. Family and friends must adjust continually to new problems and higher levels of impairment. The Department of Health and Human Services has placed a high priority on research to find both the cause and the cure for Alzheimer's Disease and related neurological disorders. A Departmental Task Force on Alzheimer's Disease was established in 1983 to stimulate and coordinate DHHS research,demonstration, training, and public information programs focused on better understanding and treatment of the disease, and on providing the medical and supportive services needed by Alzheimer's patients and their families -- in hospitals, in nursing homes, and in the community.

The activities of the Administration on Aging described in this report are an important part of the Department's efforts to meet the challenges associated with Alzheimer's Disease. In particular, the demonstration projects supported by AoA are aimed at strengthening family care and community-based services for older persons with the disease through model programs in such areas as caregiver training, family support groups, and respite care. A further emphasis is placed on public/private sector collaboration, with many of the project's closely coordinating their efforts with local chapters of the Alzheimer's Disease and Related Disorders Association, the leading private voluntary organization in the field.

The AoA-funded projects take several different approaches Two projects are broadly aimed at increasing public awareness and understanding of the disease. One, under the leadership of the Hillhaven Foundation, will conduct a series of seminars for health care professionals and forums for the general public. The other, based at the University of Southern California, will make use of a public opinion survey to develop a baseline profile of current public knowledge and perceptions concerning Alzheimer's Disease.

Five projects are demonstrating and testing distinct models of caregiver training:

- the New York City Department for the Aging will focus on the effectiveness of legal counseling;
- issues of particular concern to rural caregivers are being addressed at West Virginia University;
- researchers at the University of Chicago will evaluate the efficacy of behavioral programming techniques being administered by family and other caregivers to Alzheimer's patients;
- a team at the University of Southern California will develop, pilot, and test telephone support networks as both an instructional vehicle and a source of emotional peer support for Alzheimer's caregivers; and
- the Tri-City Community Mental Health Center in East Chicago, Indiana will seek to demonstrate church-based counseling services as a model for other communities.

Three projects offer innovative approaches to providing respite care for family caregivers, with emphases on the recruitment and training of homecare respite workers. These projects are based at the Connecticut Department on Aging, the University of South Florida, and the Alzheimer's Disease and Related Disorders Association of Eastern Massachusetts.

The two other projects funded by AoA have special if not unique features. The University of Kansas College of Health Sciences and Hospital will coordinate efforts in a four State region (Iowa, Kansas, Missouri, and Nebraska) to develop and implement model family support groups for rural areas. The second project features a State residential resource center--including a board and care home, an adult day treatment and respite program, and an evaluation unit--that will be developed under the leadership of the Bureau of Maine's Elderly.

A set of abstracts of these Alzheimer's Disease projects is appended to this report

B) Multiyear Alzheimer's Disease Initiative

As a part of AoA's participation in the Department's Task Force on Alzheimer's Disease, in FY 1984, AoA developed a multi-year strategy for the development and expansion of support services for families of older persons with Alzheimer's Disease. To implement this strategy, AoA developed a special initiative for joint efforts between the AoA Regional Offices and the Long Term Care Gerontology Centers to train State and Area Agency on Aging personnel about Alzheimer's Disease and the development and expansion of family support groups.

The AoA Regional Offices and the Long Term Care Gerontology Centers, in collaboration with the Alzheimer's Disease and Related Disorders Association (ADRDA), provided Regionwide training sessions for State Agencies on Aging and other interested parties in each of the ten Regions. Following the training sessions, 49 States elected to implement special Alzheimer's Initiatives on a Statewide basis. Most of these States replicated the Regional training sessions for Area Agency and service provider personnel.

To assist State and Area Agencies on Aging in carrying out this initiative, two of the Long Term Care Gerontology Centers and the Aging Health Policy Center developed a comprehensive technical assistance package which was widely disseminated. During FY 1985, 6,000 copies of the technical assistance package were supplied to State and Area Agencies on Aging, State and local governmental agencies, Community Health and Mental Health Centers, hospitals, long term care facilities and universities. The high demand for this material resulted in the printing and dissemination of an additional 4,000 sets in FY 1986, which is a total of 10,000 copies disseminated nationwide.

During FY 1985, with the help of the Regional Offices and the State and Area Agencies on Aging, AoA continued to build upon FY 1984 activities to expand the availability of supportive services for families of older persons with Alzheimer's Disease. Special emphasis was placed upon the development and expansion of respite care services for the caregivers of older persons with Alzheimer's Disease.

Regional Offices consulted with States to determine the current status of respite care and to plan future activities. During the fourth quarter of the Fiscal Year, Regional Offices held conferences and training sessions with State staff and other interested parties about implementing respite care activities.

Approximately $250,000 of Title IV Discretionary Grant funds were used to carry out Regional Office initiatives relating to the expansion of supportive services for older persons with this disease and their families. Three of the Long Term Care Gerontology Centers developed technical assistance materials about the "state-of-the-art" and different approaches for implementing respite care services which will be disseminated to State and Area Agencies on Aging during FY 1986.

In FY 1985, Governors formed State level task forces to study the availability of services for Alzheimer victims in the following 12 States: Connecticut, New Hampshire, New Jersey, Delaware, Maryland, Kentucky, Illinois, Minnesota, Ohio, Wisconsin, Texas and Kansas. State legislative activity was reported in the following 11 States with seven of these States appropriating funds for support services for older persons with this disease.

Massachusetts	proposal for tax relief for caregivers;
Maine	funds appropriated for residential care demonstration;
Vermont	funds for respite care services;
New Jersey	funds for treatment center, services and other activities;
North Carolina	funds for services;
Illinois	funds for services;
Minnesota	funds for the task force;
Wisconsin	funds for services;
Missouri	legislative hearings;
California	funds for services; and
Washington	funds for services.

State and Area Agencies have worked very closely with ADRDA Chapters in continuing to sponsor and conduct numerous training sessions and conferences on Alzheimer's Disease. This has resulted in the development of a number of new family support groups and the expansion of existing community services for victims of this disease. In several instances, Alzheimer's Disease was the theme of the annual Governor's Conferences on Aging held during 1985.

The AoA Philadelphia Regional Office co-sponsored a Regional Mental Health Conference on Alzheimer's Disease which attracted over 700 participants in December, 1985. This conference resulted in the formation of a Regionalwide coalition of State and Area Agencies, Community Mental Health Programs, and ADRDA Chapters which are undertaking specific missions in each of the six States in Region III.

AoA FY 1985 NEW AWARDS FOR ALZHEIMER'S DISEASE PROJECTS

PROJECT ABSTRACT

Project Title	Grant Number
A Residential Resource Center Supporting Formal and Informal Caregivers to Alzheimer's Disease Patients	90-AM-0120

Project Director and Grantee

Particia A. Riley, Director
Bureau of Maine's Elderly
Dept. Human Services
State House, Sta. #11
Augusta, ME 04333 207/289/2561

Project Summary

This project will establish a State-wide model resource center for professional and informal caregivers of victims of Alzheimer's Disease and related disorders. The center will include a 20 bed boarding home and an adult day care and respite program for 60 patients whose operation will be funded by the State. AoA will fund the evaluation component as well as the training and technical assistance efforts, which will be available on-site for 500 formal and informal caregivers.

AoA FY 1985 NEW AWARDS FOR ALZHEIMER'S DISEASE PROJECTS

PROJECT ABSTRACT

Project Title	Grant Number
A Model Respite Care Program for Alzheimer's Disease Victims and Their Families	90-AM-0019

Project Director and Grantee

Alice Gilbert
Connecticut State Department on Aging
175 Main Street
Hartford, CT 06106 203/566-7728

Project Summary:

Under this project, the Connecticut Department on Aging, in cooperation with interfaith volunteer caregiver training programs and CCCI, a State-wide licensed case management agency, will develop a model respite care program for Alzheimer's Disease victims and their families. Approximately one hundred person will be recruited and trained in specific respite care techniques and skills. These people will then be available for employment by the families of Alzheimer's Disease victims on an as-needed basis. The Department on Aging will publicize the project, highlight the availability of newly trained respite care workers, and evaluate the project's impact. CCCI will oversee the project after the demonstation phase is concluded. The program package can be replicated throughout the country.

AoA FY 1985 NEW AWARDS FOR ALZHEIMER'S DISEASE PROJECTS

PROJECT ABSTRACT

Project Title:	Grant Number:
Strengthening Community Support for Alzheimer's Disease Victims and Their Families	90-AM-0116

Project Director and Grantee

Dorothy Brodnax
President
Hillhaven Foundation
1835 Union Ave., Suite 111
Memphis, TN 38104 901/274-8428

Project Summary:

This project will provide both the general public and the health care community up-to-date information and materials on Alzheimer's Disease and techniques for coping with it. Through a series of 30 seminars for health care professionals and 30 public forums in different communities, the project will reach 6,000 to 8,000 persons directly, and through them have a multiplier effect on many thousands more, including both Alzheimer's Disease patients and their families.

AoA FY 1985 NEW AWARDS FOR ALZHEIMER'S DISEASE PROJECTS

PROJECT ABSTRACT

Project Title	Grant Number
Cooperative Approach to Information Dissemination and Development of Support Groups in Rural Areas	90-AM-0121

Project Director and Grantee

Linda Redford, Ph.D.
University of Kansas College of
Health Sciences and Hospital
Long Term Care Gerontology Center
39th St. and Rainbow Blvd.
Kansas City, KS 66103 913/588-1210

Project Summary

This project will focus on practical issues related to identifying and assisting cognitively impaired rural elderly and provide indepth training for service providers and family members at 12 sites within HHS Region VII. These trained persons will, in turn, develop rural family support groups and disseninate information Alzheimer's Disease and related disorders in their geographic areas.

AoA FY 1985 NEW AWARDS FOR ALZHEIMER'S DISEASE PROJECTS

PROJECT ABSTRACT

Project Title	Grant Number
Training and Placing In-Home Respite Care Workers for Alzheimer's Patients	90-AM-0122

Project Director and Grantee

Lillian Middleton
Suncoast Gerontology Center
University of South Florida
12901 North 30th Street, MDC Box 50
Tampa, FL 33612 813/974-3100

Project Summary:

This project will demonstrate the feasibility and effectiveness of recruiting, training and placing respite care workers with families of Alzheimer's patients, and prepare and distribute to the aging network practical training materials for establishing similar programs throughout the nation. This project will seek to ease caregiver burden, delay institutional placement, and reduce costs, both public and private, for long-term care services.

AoA FY 1985 NEW AWARDS FOR ALZHEIMER'S DISEASE PROJECTS

PROJECT ABSTRACT

Project Title	Grant Number
Improving the Capacity of Primary Caregivers to Care for Rural Elderly Persons with Alzheimer's Disease and Other Related Disorders	90-AM-0124

Project Director and Grantee

Lucille Nahemow, Ph.D.
West Virginia University Gerontology Center
Chestnut Ridge Professional Bldg., Suite 12
Morgantown, WV 26506 304/293-2081

Project Summary:

This project will improve the ability of primary caregivers to support relatives with Alzheimer's Disease and other related disorders. Issues of particular concern to rural caregivers and families will be addressed. Intervention strategies will be evaluated and their usefulness in dealing with individual patient needs at various stages will be determined. The results will increase knowledge about caring for Alzheimer's patients in rural areas. Findings will be disseminated to other rural areas of the country.

AoA FY 1985 NEW AWARDS FOR ALZHEIMER'S DISEASE PROJECTS

PROJECT ABSTRACT

Project Title	Grant Number
Telephone Network for Alzheimer's Caregivers: An Instructional Package for Peer Support	90-AM-0130

Project Director and Grantee

Jon Pynoos, Ph.D.
Director
Institute for Policy and Program Development
Andrus Gerontology Center
University of Southern California
University Park MC-0191
Los Angeles, CA 90089-0191 213/743-5981

Project Summary:

This project will develop, pilot, and test telephone support networks for the caregivers of victims of Alzheimer's Disease. This instructional program is designed for caregivers who cannot attend weekly group meetings, who are geographically dispersed, or who are resistant to traditional forms of psychological help. Tests of program effectiveness are an increase in social support as well as in caregiver and communications skills, accompanied by decreased burden, depression, and anxiety.

AoA FY 1985 NEW AWARDS FOR ALZHEIMER'S DISEASE PROJECTS

PROJECT ABSTRACT

Project Title	Grant Number
Alzheimer's Legal Support Project	90-AM-0144

Project Director and Grantee

Janet S. Sainer
Commissioner
New York City Department for the Aging
2 Lafayette Street
New York., NY 10007 212/577-0829

Project Summary:

This project will demonstrate an innovative replicable model for expanding the Aging Network's capacity to assist caregivers of Alzheimer's Disease patients to deal with legal problems stemming from the patient's progressive impariment. There are 4 components: 1) training of law students, lawyers, and Department staff; 2) provision of legal information; 3) increasing caregiver awareness of long-range legal/financial concerns; 4) improving the ability of AAAs to assist Alzheimer's patients and caregivers.

AoA FY 1985 NEW AWARDS FOR ALZHEIMER'S DISEASE PROJECTS

PROJECT ABSTRACT

Project Title	Grant Number
An Alzheimer's Disease Partnership for Community-Based Respite	90-AM-0162

Project Director and Grantee:

Joan Hyde, Ph.D.
The Alzheimer's Disease and Related Disorders
Association of Eastern Massachusetts
20 Park Plaza, Suite 636
Boston, MA 02116 617/574-9394

Project Summary

This project combines the resources of ADRDA units, Area Agencies on Aging, and service providers in 1) improving the quality of care for Alzheimer's victims and their families; 2) decreasing stress on family caregivers; and 3) increasing cost effectiveness of care in the least restrictive setting. Among the innovative services to be undertaken by these community-based partnerships is a model recruitment and training program for homecare respite workers.

AoA FY 1985 NEW AWARDS FOR ALZHEIMER'S DISEASE PROJECTS

PROJECT ABSTRACT

Project Title	Grant Number
Church Based Counseling Services for Older Persons with Alzheimer's Disease and Their Families	90-AM-0163

Project Director and Grantee

Tobi Ehrenpreis
Tri-City Community Mental Health Center
3901 Indianapolis Blvd.
East Chicago, IN 46312 219/398-7050

Project Summary:

This project is designed to provide church-based counseling and advocacy services to older persons with Alzheimer's Disease and their families. Services will be delivered by volunteers, clergy, and mental health professionals. An innovative model will be established for church/community mental health center collaboration to serve Alzheimer's victims and their families.

AoA FY 1985 NEW AWARDS FOR ALZHEIMER'S DISEASE PROJECTS

PROJECT ABSTRACT

Project Title	Grant Number
Analysis of Behavioral Programming for Alzheimer's and Other Dementia Clients	90-AR-0063

Project Director and Grantee

Elsie Pinkson, Ph.D.
University of Chicago
969 E. 60th Street
Chicago, IL 60637 312/962-1176

Project Summary:

This project will evaluate the use of behavioral procedures, in combination with family and day care center interventions, in preventing institutional placement of Alzheimer's and other dementia clients. The project will be conducted in 2 or more day centers with 30 clients, 30 families, and 15 staff over a 2 year period with follow-up every 6 months. Benefits should include a decrease in early admission to nursing homes, respite for family caretakers, and evidence on the costs and feasibility of this cooperative, nonresidential care program.

AoA FY 1985 NEW AWARDS FOR ALZHEIMER'S DISEASE PROJECTS

PROJECT ABSTRACT

Project Title:	Grant Number
Establishing a Baseline Profile of Public Knowledge and Perceptions Concerning Alzheimer's Disease	90-AR-0064

Project Director and Grantee

Neil Cutler, Ph.D.
Andrus Gerontology Center
University of Southern California
Los Angeles, CA 90089-0141 213/743-6794

Project Summary

This project will develop a baseline profile of public knowledge and perceptions concerning Alzheimer's Disease. A national survey will determine the nature and extent of misperceptions and misinformation about Alzheimer's Disease and suggest specific educational and media efforts to redress the problem. This baseline national profile should lead, as well, to more systematic analysis of public knowledge and attitudes regarding Alzheimer's Disease.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Alcohol, Drug Abuse, and Mental Health Administration

Report on Family Stress and the Care of Alzheimer's Disease Victims

Robert L. Trachtenberg

Robert L. Trachtenberg
Acting Administrator, ADAMHA

February, 198[illegible]

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute of Mental Health

Family Stress and the Care of Alzheimer's Disease Victims

The 1986 Report of the House Appropriations Committee (H 99-289), dated September 26, 1985, page 83 makes the following statement:

> "The Committee is pleased that the Institute has initiated a program focusing on the family stress problems relating to the care of victims of Alzheimer's disease and the development of family care and service delivery models. The Committee expects that these initiatives will be continued in FY 1986 and the Institute will submit a report on these initiatives by February 15, 1986."

This Report is submitted in response to the Committee's request.

In April 1985 the National Institute of Mental Health issued a specialized Research Grant Announcement, "Research on Family Stress and the Care of Alzheimer's Disease Victims" soliciting applications on this topic. Applications will be accepted under this specific program through FY 1985 and 1986.

The specialized announcement solicits applications which focus on the generation of systematic information on: the nature, consequences, and interplay of stress associated with caregiving; factors associated with maintaining and enhancing family support; the identification, treatment, and management of excess disability in Alzheimer's Disease (AD) patients and strategies to maximize their functional level at all stages of the disease; the prevention of psychopathology and the promotion of mental health among family caregivers; and research on the design and delivery of services including treatment and clinical interventions for individuals with AD and for the family members who care for them.

In FY 1985, six (6) projects were funded with total costs of $841,257.

The studies currently underway in this area include:

R01 MH40483 $1[illegible],000   Caring for Demented Spouses:
Crisis vs. Adaptation
Rachel A. Pruchno

This prospective longitudinal study is assessing the differential impact which chronic dementias cause in the caregiving spouse in order to characterize those factors which may influence the intensity, duration, and frequency of negative consequences of coping with the disease process. This study is expected to provide new information relevant to identifying with specific groups of spouse caregivers who are at risk for dysfunction.

R01 MH35360 $141,218 Caring for Elders and Mental Health of Family Members
Walter S. Poulshock
Benjamin Rose Institute

This panel study is designed to look at family decisionmaking in the context of home caregiving to an impaired older relative. This research investigates the way in which families resolve problems in relation to major changes in the AD patient's status on care arrangements. The caregiving situation is examined as a process in which stress and the effects of stress have consequences for the mental health of all family members.

R01 MH37292 $182,345 Senile Dementia Patients:
Mental Health of Caregivers
M. Powell Lawton
Philadelphia Geriatric Center

This research is investigating the mental health problems associated with caregiving to clinically impaired senile dementia patients, and patients without dementia. This research has a strong focus on the quality of life of caregivers and on community dwelling and institutionalized AD patients.

R01 MH35352 $230,418 Patient Care, Sibling Relationships and Mental Health
Elaine M. Brody
Philadelphia Geriatric Center

This research is studying sibling relationships in situations in which a widowed elderly mother needs help and has two or more adult children. The aim of the research is to obtain information on the apportionment of parent care responsibilities within the family and to examine both problems and positive factors in sibling relationships related to caretaking responsibilities for elderly parents.

P50 MH40041 $ 24,000 Psychosocial Component of Clinical Research Center for the Study of Senile Dementia
Jerome A. Yesavage
Stanford University

Two preliminary studies are being conducted:

The first is an evaluation of the nature and intensity of psychological problems experienced by caregivers of AD patients, and the nature of coping strategies used by them. The second project is an intervention study focusing on the efficacy and appropriate timing of various psychotherapies given to AD spouse caretakers who suffer from major depressive disorders.

RO1 MH33779	$117,187	Stress Vulnerability in Alzheimer Patient's Families Joseph Becker University of Washington This study is examining the vulnerability to, and incidence of, depression among spouse-caregivers of Alzheimer's disease.

These grants being funded by the National Institute of Mental Health examine the problems of family caregivers from a variety of different perspectives and disciplines. Findings from these studies will lead to improving our understanding of how families make decisions in relationship to the major aspects of caregiving such as institutionalization and apportionment of care, enhance the ability of support systems to identify vulnerable caregivers at risk for developing stress related dysfunction, and establish the efficacy of various interventions designed to alleviate caregiver distress. Through the complementary approaches undertaken by these grants it is anticipated that they will achieve greater gains in the application of research findings to practice than if a single protocol were followed.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases

SPECIALIZED CENTERS OF RESEARCH IN ARTHRITIS AND MUSCULOSKELETAL DISEASES

Thomas E. Malone, Ph.D.
Deputy Director, NIH

March 1986

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

National Institutes of Health

National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases

SPECIALIZED CENTERS OF RESEARCH IN ARTHRITIS AND MUSCULOSKELETAL DISEASES

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SPECIALIZED CENTERS OF RESEARCH
IN ARTHRITIS AND
MUSCULOSKELETAL DISEASES

Executive Summary

In House Report No. 99-289, the Committee on Appropriations requested that the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) explore the feasibility of establishing specialized centers of research (SCORs) in arthritis and musculoskeletal diseases. The Committee specifically mentioned rheumatoid arthritis, osteoarthritis, and osteoporosis as high priority areas of research "which might benefit from the SCOR concept of integrating basic and clinical research in one setting." This report is submitted in response to that request.

The requested assessment of the scientific feasibility and potential benefit of establishing a program of Specialized Centers of Research in arthritis and musculoskeletal diseases has been made. This assessment determines that both the magnitude of the health problems associated with arthritis and musculoskeletal diseases and the unprecedented scientific opportunities in these fields warrant such an initiative and that the SCOR mechanism would be a valuable adjunct to the Institute's research portfolio.

The goal of specialized centers of research in arthritis and musculoskeletal diseases would be to accelerate the pace of research on their causes, progression, and treatment and to expedite the transfer of research results to improved health care. The proposed centers program would focus on rheumatoid arthritis, osteoarthritis, and osteoporosis. These diseases are three of the most debilitating of the more than 100 kinds of arthritis and related disorders, which are estimated to cost the nation over $25 billion a year. As the American population ages, the number of people affected and the economic costs are increasing. The means to reverse these trends is through research.

The Institute has noted the expressed interest of several outstanding investigators in the establishment of SCORs in these fields. If a program of such centers in arthritis and musculoskeletal diseases were initiated, it is expected that the quality of applications would be high and the competition vigorous. The initiation of a SCOR program by the Institute has been supported strongly by the NIADDK's National Advisory Council and National Arthritis Advisory Board, as well as by several professional and voluntary organizations.

Establishment of Specialized Centers of Research in arthritis and musculoskeletal diseases, specifically in rheumatoid arthritis, osteoarthritis, and osteoporosis, could supply an important impetus to the national research effort in these diseases, if additional resources were to be made available for this purpose.

SPECIALIZED CENTERS OF RESEARCH IN ARTHRITIS AND MUSCULOSKELETAL DISEASES

INTRODUCTION

In its report on the fiscal year 1986 budget for the Department of Health and Human Services, the Committee on Appropriations stated:

> "Specialized Centers of Research (SCOR) are useful mechanisms for accelerating research in areas where coordinated, multidisciplinary efforts are likely to produce rapid clinical applications of basic science advances. There are several promising areas of research in arthritis and musculoskeletal diseases which might benefit from the SCOR concept of integrating basic and clinical research in one setting, including rheumatoid arthritis, osteoarthritis and osteoporosis. Research in these areas has advanced to the point where a concentrated multidisciplinary research effort could be initiated. The Committee continues to be concerned about the need to strengthen the arthritis and musculoskeletal diseases research program, and, therefore, encourages the Institute to explore the feasibility of establishing specialized centers of research in these high priority areas. The Committee will expect a report on this matter before next year's hearings." (House Report No. 99-289, page 48)

The following report has been prepared by the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK), National Institutes of Health of the Department of Health and Human Services in response to this request.

BACKGROUND

Over 15 years of experience with SCORs, primarily in the National Heart, Lung, and Blood Institute, have confirmed their effectiveness in focusing resources on diseases of major national importance. Such centers concentrate research personnel in a multidisciplinary research environment, providing resources and facilities for advanced approaches to both laboratory and clinical science. By promoting active collaborations among scientists and disciplines, not merely informal interactions, the SCOR concept enables complex, multifaceted research challenges, such as those of major diseases within arthritis and musculoskeletal diseases, to be met by an optimal investigative team. The intimate association of laboratory and clinical research also aids the rapid translation of advances in the basic sciences into clinical applications, which, in turn, often provide a direction for new avenues of basic research. To accomplish this synergy, centers coordinate formally organized series of interacting basic and clinical research projects capable of expediting the development and application of new knowledge essential for improved diagnosis, treatment, and prevention of disease.

An assessment has been made of the value of the SCOR concept for providing leadership and increased momentum to the national research effort in arthritis and musculoskeletal diseases. This mechanism can be a valuable adjunct to the Institute's research portfolio, especially at a time when the magnitude of the health problems associated with arthritis and musculoskeletal diseases is increasing and the scientific opportunities for addressing these problems are unprecedented. It has also been determined that interest and expertise within the biomedical research community are sufficiently high to expect that an excellent system of SCORs could be established in arthritis and musculoskeletal diseases, particularly in rheumatoid arthritis, osteoarthritis, and osteoporosis. Recommendations of the NIADDK National Advisory Council, the National Arthritis Advisory Board, and professional and voluntary organizations in these fields confirm this assessment.

MAGNITUDE OF THE HEALTH PROBLEM

Arthritis and musculoskeletal diseases afflict over 44 million Americans, with an estimated economic cost to the nation of over $25 billion a year. Arthritis is the nation's primary crippler, causing increasing numbers of persons to leave work before normal retirement age. While reported to affect more than 40 percent of people over age 65, an estimated 250,000 children also have arthritis or a related joint disease. Some of these children will carry serious handicaps into adulthood.

Of the more than 100 kinds of arthritis and related disorders, rheumatoid arthritis, osteoarthritis, and osteoporosis are three of the most debilitating. Rheumatoid arthritis (RA) is the major crippling disorder among the rheumatic diseases. It is an inflammatory disorder of the joints characterized by pain, stiffness, deformation, and disability. Until very recently, little was known about the cause of this disease or the mechanisms of inflammation responsible for the pain, swelling, and thickening of tissues, and available treatment focused on symptomatic relief. Advances in understanding of the mechanisms of this disease have provided new methods to block the destructive and inflammatory processes of RA. Several effective pharmaceutical and non-pharmaceutical therapies have been developed, although many are still under investigation. One of these medications studied recently, methotrexate, previously used to treat cancer and psoriasis, seems particularly promising. There are at times, however, serious toxicities associated with use of the medicinal agents, which have prompted reservations about their long-term use. Non-pharmaceutical therapies thus far devised have only been able to relieve some of the symptoms of the disease. Improved interventions, as well as preventive and curative measures, await application of results of further research.

More than 16 million Americans have osteoarthritis, the most widespread form of arthritis. Osteoarthritis primarily affects the cartilage of the joint, causing the joint to fray, wear, ulcerate, and in extreme cases, to disappear, leaving a bone-on-bone joint. Since most individuals suffering from this disease are over 50 years of age, this health problem is expanding with the aging of the American population. Among the several forms of osteoarthritis that have been identified, however, is one which afflicts young athletes following traumatic injury. The early treatment for osteoarthritis is focused on relieving the pain by a combination of medication, rest, and exercise. Medications include aspirin and other non-steroidal anti-inflammatory drugs. In advanced cases of osteoarthritis, total replacement of a severely diseased joint in the body has become a successful treatment by skilled orthopedic surgeons. Potential savings in pain and disability, as well as health care costs, would attend development of a specific early treatment for cartilage degeneration in osteoarthritis.

In osteoporosis, a disorder in which bone mass decreases, the bones become weak and are usually vulnerable to fractures. Each year, 1.3 million fractures are attributable to osteoporosis, generating an economic burden estimated at $3.8 billion. Osteoporosis affects 15 to 20 million Americans, including over half of women above 45 years of age and 90 percent of women above age 75. Precise understanding of the mechanisms that govern this condition is lacking. Sex, age, and race are clearly identified risk factors for developing osteoporosis, but an understanding of why these are risk factors is limited.

Two leading causes of osteoporosis have been found to be deficiency of estrogen and deficiency of calcium. Further research is needed to develop the safest and most effective hormone replacement therapy and the optimal amount and form of calcium for prevention of bone loss and fractures. Adequate levels of vitamin D and weight bearing exercises are also beneficial. Further research on prevention of osteoporosis is being actively promoted by the Institute. Treatment of osteoporosis, once it has developed, however, such as stimulating formation of new bone, has not been achieved and requires additional basic research on bone metabolism.

The magnitude and scope of these health care problems warrant expedited progress in research and prompt transfer of research results into recommendations for health care. Establishment of SCORs would represent a highly effective means of accomplishing this goal.

CURRENT STATE OF RESEARCH AND SCIENTIFIC OPPORTUNITIES TO BE PURSUED

Opportunities exist for research that might lead to the discovery of the cause and cure of rheumatoid arthritis. There is a growing body of evidence implicating microorganisms--bacterial, mycoplasmal, and viral--in the cause and progression of this disease. Prevailing theory holds that these microorganisms precipitate immune responses that induce arthritic symptoms in genetically predisposed individuals. Institute grantees have reported evidence of a candidate virus as a causative agent for RA; this and other viruses associated with RA are the subject of intense scientific efforts. The NIADDK is also planning a major clinical study to search for these infectious agents.

Studies of genetic markers for RA are under way, aimed at discovering genes responsible for abnormal immune responses in arthritis. If the genetic basis or regulatory mechanism can be found that results in the aberrant immune response, therapies could be developed to restore normal immune function.

The availability of a new animal model of RA has been valuable for permitting observation of the temporal development of this disease, and has reoriented research approaches. Among the aspects of the progression of RA thus elucidated are the course of proliferation of cells lining the joint membrane, abnormal events in the immune response promoting inflammation, and the nature of the subsequent damage to cartilage. Recent findings have also pointed to a role for the nervous system, particularly substance P, in joint inflammation.

Because osteoarthritis is associated with aging, this disease is often regarded as inevitable and probably caused by wear and tear of joints. Neither of these misconceptions has been borne out by recent biochemical, clinical, or epidemiologic data. Recent epidemiologic studies, some of which were conducted at the Institute's Multipurpose Arthritis Centers, have shown that among older age groups, the prevalence of osteoarthritis does not increase with age. Important findings from biomedical research reveal major biochemical differences between aging cartilage and osteoarthritic cartilage, indicating changes in biochemical properties of the cartilage detrimental to its biomechanical integrity. Another important factor also under investigation is the ability of cartilage cells to produce degradative enzymes that have the capacity to destroy vital structural components of cartilage.

Particularly promising is the recent identification of substances responsible for the abnormal behavior of cartilage cells in osteoarthritis. There is a pressing need to increase research on the fundamental mechanisms involved in the progression of osteoarthritis. Understanding these mechanisms would present important opportunities to block the disease process at any one of a number of steps.

Some future research directions will likely include studies of joint usage. Efforts to increase muscle strength could foster increased cartilage integrity and functional status. Through research, it may be possible to develop a dose-response curve for exercise in order to foster healthy cartilage--a development that may also prove extremely useful in sports medicine.

Osteoporosis has become a focus of national public attention, in no small part because of the recent NIH consensus conference on this disease supported by the Institute. Among other items, this conference examined the risk factors associated with this disease and endorsed the preventive measures determined by research to be effective, including administration of estrogen, calcium supplementation, and exercise. Research is continuing on the utility, benefits, and risks of various forms and dosages of hormonal therapy to prevent osteoporosis in older women, particularly to determine the safest, most effective regimen for preventing bone loss and fracture. Studies are also needed to define further those populations requiring increased calcium intake, as well as the optimal dosage and timing for calcium supplementation when necessary. Implementation of such studies will require epidemiologic research to ascertain the impact of demographic and behavioral factors on bone mass and fracture frequency. The goal of all these studies would be to achieve maximal adult peak bone mass and to prevent bone loss thereafter.

Research on understanding the normal activity of newly discovered factors in the bone remodeling process is being oriented to discovering how these factors are altered in the pathogenesis of osteoporosis. New knowledge on the dynamics of this process may offer an opportunity for restoring normal function and reversing osteoporosis. Also needed are the development of reliable and cost effective means of measuring bone density for diagnosis, screening, and therapeutic monitoring of this condition.

In all three of these diseases, a multidisciplinary approach could contribute to significant research progress by fostering basic and clinical research interrelationships and interinstitutional efforts. Through the mechanism of SCORs, translation of research advances into improved health is achievable.

EXPERTISE AND INTEREST OF POTENTIAL CENTER GRANT APPLICANTS

In evaluating the feasibility of establishing a SCORs program, the availability of talented and interested investigators was carefully considered. This evaluation has revealed a pool of highly capable potential leaders for SCORs devoted to these diseases. Several productive investigators have expressed strong interest in and ideas for developing SCORs in arthritis and musculoskeletal diseases. Many of these investigators would bring extensive skills in the sophisticated research techniques of immunology, genetics, and molecular and cell biology needed for rapid advances in arthritis and musculoskeletal diseases research. There is therefore sufficient reason to believe that the quality and scientific merit of center grant applications would be high and the competition for awards vigorous.

RECOMMENDATIONS OF PROFESSIONAL AND VOLUNTARY ORGANIZATIONS

The research centers concept is strongly supported by the academic research and clinical community in arthritis and musculoskeletal diseases. The National Arthritis Advisory Board in its 1984 Annual Report recommended:

> "Consistent with its testimony before Congress in April 1984, the Board believes that funding for Specialized Centers of Research (SCORs) will supplement the rigorous and successful programs that have evolved under the Multipurpose Arthritis Centers (MAC) concept. Specialized Centers of Research provide for interdisciplinary research targeted to a particular rheumatic disease."
>
> "The Research Subcommittee concurs with the Arthritis Centers Subcommittee that special emphasis should be given to recommending SCOR grants which would capitalize on existing geographic aggregates of basic and clinical investigators capable of using advanced technology to pursue research on specific diseases."
>
> "The Board believes that SCORs will provide a mechanism for funding new programs in the field of arthritis and that this funding should be in addition to an increase in MAC funding,

> not a substitute for it....The Board strongly recommends that NIH continue its commitment to support MACs."

These concepts have also been supported by the Institute's National Advisory Council, the American Rheumatism Association, the Orthopaedic Research Society, the American Academy of Orthopaedic Surgeons, and the Arthritis Foundation. In formal workshops and conferences sponsored by the Institute over the past two years, experts in rheumatoid arthritis, osteoarthritis, and osteoporosis have emphasized repeatedly the need for multidisciplinary, and possibly interinstitutional, research approaches to these complex diseases. They have also determined that the state of the science in these three diseases would benefit greatly from a coordinated effort that incorporates both basic and clinical investigation while facilitating rapid transfer of research results to health care.

MULTIPURPOSE ARTHRITIS CENTERS

The Multipurpose Arthritis Centers (MACs) currently funded by the NIADDK provide support for facilities and special projects which facilitate and stimulate biomedical research supported by traditional research grants from NIH and other sources. Each Multipurpose Arthritis Center is therefore expected to maintain a substantial base of research grant support as a prerequisite for receiving a center grant award. Because of the diverse sources of these investigator-initiated awards, this base of research may comprise either basic or clinical studies, or both, in any one of a number of arthritic conditions. Biomedical research projects supported by center grant funds are almost exclusively developmental and feasibility studies designed to enable investigators to explore highly innovative scientific approaches to arthritis research. These studies have frequently initiated highly meritorious and productive research efforts later supported by NIH and other grant awards.

In addition to its strong research component, each Multipurpose Arthritis Center also develops innovative methods for the prompt and effective application of available knowledge for the treatment of patients with arthritis and related musculoskeletal diseases. These activities lead to exemplary programs of professional, patient, and public education, as well as related activities emphasizing health services research. The centers are distributed nationwide and comprise a broad scope of efforts in many diverse arthritic and musculoskeletal diseases.

SCORs would provide an important complement to existing centers support, and not an alternative to it. In contrast to MACs, each of which incorporates research on a diversity of diseases, a SCOR would direct its research exclusively to a specified major disease or health problem. SCORs would establish multidisciplinary and interdisciplinary research groups under unified leadership. The research focus of each SCOR would be designated by the Institute, ensuring that additional resources would be directed to the critical health problems of rheumatoid arthritis, osteoarthritis, and osteoporosis.

The following table illustrates some of the differences between Specialized Centers of Research and Multipurpose Arthritis Centers:

SPECIALIZED CENTERS OF RESEARCH	MULTIPURPOSE ARTHRITIS CENTERS (Comprehensive Centers)
Research Directed to a Specific Disease or Health Problem (e.g., Osteoarthritis)	Diverse Areas of Arthritis and Musculoskeletal Diseases
Designated by Institute	Selected by Applicant
Multidisciplinary/ Interdisciplinary	
Series of Biomedical Research Projects	Biomedical Research Projects Supported by Other Grants (NIH and Others)
Basic and Clinical Research	Basic and/or Clinical Research
No Developmental and Feasibility Studies	Developmental and Feasibility Studies (pilot, small) in: Biomedical Research Educational Research Community/Health Services Research
No Educational or Community/ Health Services Research Projects	Innovative Educational and/or Community/Health Services Research Projects

PROPOSAL TO ESTABLISH SCORS IN ARTHRITIS AND MUSCULOSKELETAL DISEASES

A consensus has developed among NIADDK'S advisory groups, such as its National Advisory Council and National Arthritis Advisory Board, as well as a broad spectrum of professional and advisory groups, that SCORs in arthritis and musculoskeletal diseases could be a valuable adjunct to existing research programs in this area. Particularly in rheumatoid arthritis, osteoarthritis, and osteoporosis, the magnitude of the health problem is great and the scientific opportunities commensurate and unprecedented. Highly productive investigators could be expected to apply for SCOR center grants focused on these major diseases. As concluded by the National Heart, Lung, and Blood Institute, based upon an evaluation of 15 years' experience with SCORs, such centers are of proven value in furthering and enhancing research progress on diseases of major national importance.

It is reasonable to conclude that, should additional resources be available for this purpose, an effective and productive program of Specialized Centers of Research could be initiated in rheumatoid arthritis, osteoarthritis, and osteoporosis. Such a program would include a minimum of three research centers for each disease. Three centers on a given disease would provide a critical mass of investigators, permitting fruitful collaboration and cross-fertilization of ideas. With regard to clinical studies, such a network of centers is necessary to produce a substantial impact on the field and involve sufficient patients to achieve statistically significant results. There are sufficient grounds to believe that a SCOR program could form the vanguard of the research effort in these diseases; no one center team could be expected to address more than a few of the innovative leads available for pursuit. In the future, other diseases of great importance to the nation could be added to the SCOR program, as resources become available.

CONCLUSION

The SCOR concept has provided a very successful mechanism for accelerating research in several areas of scientific investigation. Establishment of a program of SCORs in arthritis and musculoskeletal diseases has been determined to be scientifically feasible and warranted by newly developed scientific opportunities. Support of the Institute's National Advisory Council and National Arthritis Advisory Board, as well as the professional and biomedical research communities for this initiative is strong. Should additional resources be available for this purpose, an effective and productive program of Specialized Centers of Research could be initiated in rheumatoid arthritis, osteoarthritis, and osteoporosis, with a minimum of three research centers for each disease. Through the establishment of SCORs, clinical and basic research advances may ultimately lead to new, effective interventions for these widespread, debilitating diseases.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

REPORT ON ASBESTOS
IN THE NORTH AND SWITZER BUILDINGS

February 1986

REPORT ON ASBESTOS IN THE NORTH AND SWITZER BUILDINGS

The building materials used during initial construction of the North Building and Switzer Building included asbestos containing material (ACM) as a component of the insulation on pipes (water and steam) and air ventilation ducts. Of primary concern to building occupants is the presence of ACM on the interior pipes servicing window inductor boxes (WIB) in every office with an exterior window. Also, ACM is located on the exterior surfaces of pipes and ducts in the mechanical rooms and the penthouse areas.

HHS has organized an Asbestos Task Force (ATF) composed of representatives of the separate organizations within the Agency. The ATF includes representatives of both management and the unions. Regular ATF meetings occur every second week, and special meetings are called as needed. The ATF has been effective in working with the GSA building manager to implement an effective control program for the ACM.

The ATF has also been instrumental in securing an external certified industrial hygienist (CIH) to provide independent oversight of the asbestos control and abatement work performed by GSA and its contractors. This arrangement has produced a greater level of communication between these separate parties, and has allowed the development of a planned approach to the control program for these two buildings.

An asbestos abatement project has recently begun to remove and dispose of the asbestos insulation within all of the window inductor boxes in the two buildings. (One-third of the Switzer Building window inductor boxes had formerly been structurally enclosed and are not covered by this contract effort.) The abatement contract schedule calls for approximately 1,900 window inductor boxes units to be treated within 6 months (of 11/85). Work is progressing satisfactorily on this contract and is expected to be completed by the end of May 1986.

Another aspect of potential concern are events which arise within the two buildings that may disturb or release ACM into the air. The Certified Industrial Hygienist is also consulted when any such situation arises during normal use of the buildings. One such event, which occurred in August 1985, concerned the potential of asbestos fiber release during work on a chiller condensation line in a mechanical room. There was concern that air supply to certain office zones may have been contaminated. The HHS management, when advised of the situation, evacuated the affected areas and arranged for an extensive air monitoring study to verify the safety of those offices for the subsequent return by employees. The Asbestos Task Force was kept constantly advised of events as they took place. It was found that no hazardous emissions had occurred, and due to management's prudent actions, no potential for hazardous exposure was present. Asbestos abatement actions have also been effective in producing control of ACM in the mechanical rooms, the pipe chases, and in the penthouse areas where the primary air handling units are located. Significant progress has been made in achieving a tight, effective control program.

In summary, the HHS strategy for achieving safety of its employees has been active and rigorous. Potential locations of ACM within the North and Switzer Buildings have been sought out and identified. Control actions have been accomplished via a cooperative plan of action developed between HHS and GSA. The total risk to HHS employees due to potential asbestos exposure has been reduced as a result of the Agency's control program.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
National Institutes of Health

Health and Behavior Research Supported by the NIH, FY 1983 to FY 1985

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

National Institutes of Health

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Health and Behavior Research Supported by the National Institutes of Health, FY 1983 to FY 1985

Executive Summary

In House Report 99-289, the Committee on Appropriations requested that "...the NIH review research grants related to the link between health and behavior awarded by each Institute during the past three years, and report to the Committee on where research initiatives in this area have occurred, the total funding for health and behavior research over this period for each Institute, and future priorities at each Institute for behavioral research."

The NIH has a long history of support for research at the interface among the behavioral and biomedical sciences. Most recently, during FY 1983-1985, support for extramural and intramural research and research training on health and behavior has grown from approximately $66 million to $105 million. The NIH played a key role in supporting the ideas and proposals espoused in the Institute of Medicine's conferences and report on Health and Behavior as well as in the proposed PHS Initiative on Health and Behavior. Moreover, in 1981 the NIH established the Working Group on Health and Behavior in order to facilitate programmatic coordination and development, enchance the exchange of scientific information, and to make recommendations to the the Director, NIH, on health and behavior research.

Nearly all of the Institutes at the NIH have programs that support or conduct research relevant to health and behavior and, in keeping with their mission, they have issued Program Announcements and Requests for Applications encouraging these endeavors. These programs demonstrate that behavioral and social factors are important in the promotion of health, the prevention and treatment of disease, and in developmental and aging processes themselves. NIH-supported research shows, for example, that behavior and lifestyle play a significant role in controlling high blood pressure, stabilizing insulin levels in diabetics, lessening osteoporosis in the elderly through exercise, preventing periodontal disease through brushing and flossing of teeth, avoiding alcohol and drugs, practicing care in vehicular use, discouraging risk-taking in children, and in ceasing tobacco use.

Health and Behavior Research Supported by the National Institutes of Health, FY 1983 to FY 1985

INTRODUCTION

In its report on the Fiscal Year 1986 budget for the Department of Health and Human Services, the House Committee on Appropriations for the Departments of Labor, Health and Human Services, and Education, and Related Agencies stated:

> The Committee has a continuing interest in research on the role of behavioral factors in the promotion of health and the treatment and prevention of disease. Last year, the Committee suggested that the recommendations of the Surgeon General's report, Healthy People and the Institute of Medicine's Health and Behavior be pursued at the earliest possible opportunity. These reports indicate that 7 of the leading 10 causes of death in the United States, accounting for 50% of all mortality, are in part behaviorally determined. Both reports also identified a number of promising areas of research on behavioral factors in the treatment and prevention of illness. Basic behavioral research supported by NIH is relevant to understanding the mechanisms of disease processes. For example, research supported by the National Cancer Institute in the new area of psycnoneuroimmunology holds promise of important breakthroughs in understanding how psychological stress may affect the development and progress of cancer, and can be expanded to help better understand such new diseases as AIDS. Other NIH Institutes supporting studies on the contributions of behavioral factors to health promotion and disease prevention include The National Institute of Child Health and Human Development, The National Heart, Lung, and Blood Institute, The National Institute of Dental Research, The National Institute on Aging, and the National Eye Institute. The Committee urges NIH to provide a more coordinated effort for research on health and behavior.
>
> The Committee requests that NIH review research grants related to the link between health and behavior awarded by each Institute during the past three years, and report to the Committee on where research initiatives in this area have occurred, the total funding for health and behavior research over this period for each Institute, and future priorities at each Institute for behavioral research. (House Report No. 99-289, pp. 37-38)

The following report has been prepared by the National Institutes of Health, Department of Health and Human Services in response to this request.

Background

The National Institutes of Health (NIH) has a long history of support for research at the interface among the behavioral and biomedical sciences. Most recently, during the past three fiscal years, NIH's support has grown from approximately $66 million to $105 million. (See Table 1.) A manifestation of NIH's commitment to research on health and behavior was the key role played by the NIH in supporting the Institute of Medicine's conferences and report on "Health and Behavior: A Research Agenda" and in the proposed PHS Initiative on Health and Behavior. In order to promote this line of research, the NIH Working Group on Health and Behavior was established in December, 1981, with the charge:

> To share across all NIH Institutes programmatic and scientific information of mutual interest on health and behavior;
>
> To provide a forum for consideration of new developments at NIH;
>
> To keep abreast of parallel activities of other groups in the public and private sectors;
>
> To make recommendations as appropriate to the Director, NIH.

This group has members from most Institutes at NIH and meets monthly. The group exchanges information and plans, arranges seminars, compiles information as requested by the Director, NIH, makes recommendations to him from time to time, and supplies information to the NIH and the larger scientific community. In an effort to improve coordination among the Institutes, the Working Group on Health and Behavoir is currently a) reviewing research conducted by each Institute, b) organizing scientific seminars on topics of relevant to program development in several Institutes, and c) developing common coding schemes for grant applications. Thus, the group is the focal point for coordinating research programs on health and behavior within NIH and between the NIH and other agencies.

As a guide for continuing program development and as a tool for use by NIH in tracking program activities and budgets, the Working Group developed the following statement on health and behavior research:

> As life-style and behavioral factors have been identified as the major causes of death in the U.S., and as the effects of psychosocial and behavioral variables on biological processes have come to be recognized, the social and behavioral sciences are making increasingly important contributions to understanding of the promotion of health and the prevention, treatment, and cure of disease. Many medical problems, including heart disease and cancer, appear to be influenced by behavioral and social variables, such as habits of living; by social environments (work, family, community); and by what has been termed psychosocial stress. A wide range of NIH-supported studies deal with three types of processes linking behavior to physical illness: (1) health-impairing habits and life-styles, such as smoking, heavy drinking, lack of exercise, poor diet, and poor hygienic practices; (2) reactions to illness, including minimization of the significance of symptoms, delay in seeking medical care, and failure to comply with treatment and rehabilitation regimens; and (3) direct alterations in tissue function through the brain's influence on hormone production and other physiological responses to psychosocial stimuli, particularly stress.

This statement was employed by the Institutes at NIH in preparing the narrative and budgetary descriptions of health and behavior supported by them during the Fiscal Years 1983, 1984, and 1985, which comprise the remainder of this report.

OFFICE OF THE DIRECTOR, NIH

With the tremendous progress made in the infectious disease area in this century, chronic diseases have become more dominant. It has now become evident that many of these disorders are behavior-related. In fact, as the Institute of Medicine has noted, diseases in which behavior may play a significant role -- cancer, cardiovascular disease, mental disorders, accidents, and violence -- constitute "a major component of the current burden of illness in the United States and other developed countries ... and have a dominant position in causes of mortality and morbidity." It is estimated that "as much as 50 percent of mortality from the ten leading causes of death in the United States can be traced to lifestyle."

For these reasons, biobehavioral considerations play a major role in the DHHS Prevention Initiative, launched in 1979. The definition of prevention adopted by the NIH, in fact, specifically cites: "Development of behavioral interventions to prevent disease occurrence or progression of a symptomatic disease." In addition, nearly all of the 15 Prevention Priority Areas enumerated in Healthy People have a strong behavioral orientation (e.g., Smoking and Health, Improved Nutrition, Misuse of Alcohol and Drugs, High Blood Pressure Control, Sexually Transmitted Diseases, Family Planning).

The NIH continues to make disease prevention and health promotion a major priority area, including health and behavior studies targeted toward modifying lifestyle that could help reduce disease morbidity and mortality. The Office of Disease Prevention, Office of the Director (OD/NIH), is coordinating efforts with the NIH Working Group on Health and Behavior to encourage the research community to submit proposals related to health and behavior, particularly in those areas recommended by Healthy People. Nearly all of the NIH Institutes and Divisions have issued Requests for Applications (RFA's) dealing exclusively, or in part, with research on behavioral modification in the reduction of disease incidence.

The following steps, undertaken during the past few years, are illustrative of the commitment to behavioral and social science research relative to disease prevention and health promotion:

(1) increased efforts in disease prevention and health promotion, including creation of the NIH Coordinating Committee on Disease Prevention and Health Promotion, which meets monthly and includes representation by all Bureaus, Institutes, and Divisions (BIDs);

(2) invited the Chairman of the NIH Working Group on Health and Behavior to serve as the liaison member to the NIH Coordinating Committee on Disease Prevention and Health Promotion;

(3) co-sponsored with the DHHS Office of the Assistant Secretary for Health the "Research in Prevention" meeting to be held in 1986 that will include the most contemporary research relevant to health and behavior;

(4) encouraged the seminar series on health and behavior issues;

(5) maintained continuing communication of pertinent biobehavioral research information and program ideas within NIH and with the DHHS Alcohol, Drug Abuse, and

Mental Health Administration (ADAMHA) and other agencies; and

(6) encouraged the issuance of new RFA's by all BID's to solicit outstanding research proposals in a broad range of disease prevention areas including many in the behavioral and social sciences.

To augment and accompany the statement on health and behavior research prepared by the NIH Working Group on Health and Behavior, the following five specific areas for categorizing NIH research on health and behavior have been identified. This categorization is intended to aid NIH program staff in determining how research can address the role that human behavior plays in preventing and curing disease. The five categories are:

(1) biological bases of behavior;

(2) behavioral determinants and consequences of disease;

(3) behavioral aspects of risk factors and their modification;

(4) behavioral development area of childhood including factors involved in childhood injury and its prevention; and

(5) behavioral aspects related to aging and coping (including differences in subsets of a population).

The NIH commitment to research on health and behavior is affirmed by its increasing annual expenditures on such research (Table 1). Each BID develops behavioral and social research programs appropriate to its mandate while continuing to encourage the submission of high-quality applications pertinent to the Health and Behavior Initiative.

In addition, the NIH Consensus Development Conference Program, designed to assess the safety and effectiveness of important new treatments and technologies, has addressed many issues having relevance to biobehavior. Some of these have included conferences addressing breast cancer and cervical cancer screening, surgical treatment for morbid obesity, control of cholesterol levels, high blood pressure control, osteoporosis, mood disorders, travelers' diarrhea, and the use of smokeless tobacco, among others. Upcoming 1986 consensus conferences will address the impact of routine testing for AIDS antibodies (HTLV-III) in blood donors and home monitoring for infantile apnea (temporary cessation of breathing).

NATIONAL CANCER INSTITUTE

The National Cancer Program (NCP) was created by the National Cancer Act of 1971. The mission of the National Cancer Institute (NCI) is defined by this Act and the latest amendments to the Act as follows:

> Sec. 402. The National Cancer Program shall consist of (1) an expanded, intensified, and coordinated cancer research program encompassing the research programs conducted and supported by the Institute and the related research programs of the other research institutes and including an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens and (2) the other programs and activities of the Institute.

In addition to the NCP's focus on cancer prevention through environmental and occupational studies, the Congress identified two other areas of emphasis. These areas are (1) basic research programs, rather than targeted research programs, funded primarily through contracts, and (2) education of health professionals and the general public concerning both the factors that apparently lead to a higher risk of cancer and ways to avoid them.

In order to achieve its legislative mandate, the NCI has as its overall goal to reduce cancer incidence, morbidity, and mortality. Furthermore, recently NCI announced a time-targeted goal to reduce cancer mortality rates by 50% by the year 2001.

Most scientists now believe that the majority of cancer is environmentally induced (80-90%) and, within that fraction, a major proportion is due to lifestyle. Therefore, a considerable emphasis is now being placed on the prevention of cancer. It is believed that as much as 25% of today's cancer mortality rates could be eliminated through prevention, particularly by achieving a marked reduction in smoking prevalence and specific dietary modifications.

In the case of smoking, the plan to achieve this end involves reducing the percent of adults who smoke from the 1983 level of 34% (male and female combined) to 15% or less by the year 2000; and reducing the percent in that same time period of youths who smoke by age 20 from 36% (1983) to 15% or less. In regard to diet, the plan calls for a reduction in total fat consumption from 40% to 25% or less of total calories, and simultaneously increasing the average consumption of fiber from 8-12 gms/day to 20-30 gms/day.

It is also believed that another reduction in cancer mortality could be achieved by increasing the percent of women (ages 50-70) who have annual physical breast examinations and mammography from 45% for physical examination alone and 15% for mammography to 80% for each, and by increasing the percentage of women who have a Pap smear every three years from 79% to 90% (ages 20-39) and from 57% to 80% (ages 40-70) and from achieving an increase in the adoption of state-of-the-art cancer treatment throughout the U.S. In all of the above, the behavior change of individuals and systems is required.

The current NCI organization addresses three major components: cancer research, both basic and clinical, cancer resources and cancer prevention and control. These components are administered by four NCI program divisions: the Division of Cancer Biology and Diagnosis, the Division of Cancer Etiology, the Division of Cancer Treatment, and the Division of Cancer Prevention and Control. In FY 1985, the NCI expended about $22.6 million on health and behavior research. Within the NCI, the Division of Cancer Prevent and Control (DCPC) has the primary responsibility for behavioral research because it is through this Division that the Institute's prevention and control activities are related to lifestyle and other environmental modifications are carried out. Nevertheless, health and behavior studies are also carried out in other NCI organizational units. Studies in cancer therapy compliance, reduction of patient distress in undergoing cancer therapy, psychological effects of long term cancer therapy and targeted neuropsychological studies are being supported by the Division of Cancer Treatment and a number of health informational/health educational activities are implemented in the Office of Cancer Communications in the Office of the Director, NCI.

In DCPC health and behavioral studies are evident in all three program areas: the Prevention Program, the Centers and Community Oncology Program and the Cancer Control Science Program.

Current Initiatives

PREVENTION PROGRAM

The Prevention Program focuses on the introduction, application and evaluation of effective and practical cancer control intervention strategies testing micronutrient and macronutrient dietary formulas to prevent cancer.

Chemoprevention (micronutrients), is the use of natural and synthetic chemicals to reduce the incidence of cancer. Current emphasis include studies on the consumption and usage of chemopreventive agents in the context of human intervention trials (clinical trials), and studies of toxicity and agent applications. Many of these studies require a behavioral science research perspective, particularly in relation to compliance in agent utilization.

Diet and Nutrition (macronutrients) studies seek to identify foods and dietary habits that may either induce, promote or inhibit cancer. Current emphasis include studies to assess and measure dietary factors in the context of human intervention trials (clinical trials) and studies of toxicity in the context of large-scale human intervention research. Examples of behavioral initiatives here include studies of protocol compliance in a low fat diet trial in women at high risk for breast cancer, development of methods for improving the quality of reported dietary and health behavior, and studies aimed at developing and implementing methods and strategies for dietary modifications associated with reduction in risk of disease.

CENTERS AND COMMUNITY ONCOLOGY PROGRAM

The Community Oncology Program focuses on the introduction, application and evaluation of effective and practical cancer control intervention programs in community settings. Primary emphasis is on the integration and involvement of community physicians and allied health professionals in promoting state-of-the-art cancer management strategies and the promotion of linkages between community practitioners/hospitals and other regional resources for the same. Objectives are to (1) reduce the time between research advances in prevention, detection, and patient management, and their application in community settings; and (2) expand and extend the cancer care knowledge and applications bases. Current behavioral initiatives include community intervention studies to: improve survival and minimize the side effects of cancer therapy; utilize current levels of knowledge, attitudes, and practices of patients, families, physicians and other health professionals involved in cancer care; influence positively compliance with prescribed management regimens and participation in clinical research; improve pain management in cancer patients; improve patient outcome in the elderly; increase the effectiveness of the primary physician in the delivery of cancer care at the community level; and improve patient participation in clinical research studies.

CANCER CONTROL SCIENCE PROGRAM

The Cancer Control Science program focuses on the planning, implementation and evaluation of cancer control research interventions. This program contains four organizational units: cancer control applications, health promotion sciences, occupational cancer and cancer training.

The Cancer Control Applications program ensures that research results are effectively applied to the Nation's cancer control needs in a timely manner. The primary objective here is to identify opportunities for, and facilitate the application of effective cancer control interventions. Current emphases include high-priority intervention research that is aimed at meeting Year 2000 goals. This goal will be achieved through the funding of Cancer Control Research Units (CCRU) and Cancer Control Science Programs (CCSP). These are large multidisciplinary centers of research excellence, each carrying out multi-year intervention research studies. Thirty to 45% of activities in these centers are concerned with health behavioral issues. Examples include: studies to identify the reasons why deaths occur from those cancers for which early detection and/or effective treatment technology already exists in order to design intervention strategies to reduce those avoidable mortalities.

Health Promotion Sciences are concerned with the development and testing of intervention strategies to modify personal, social, and lifestyle factors known to contribute to the development and/or increased risk of cancer. Current emphases include: (1) modifying behavior patterns and lifestyle of high risk populations, behavioral factors associated with the successful practice of early detection strategies and participation in screening programs, counterproductive patient behavior during cancer treatment, and delay behavior of symptomatic individuals; (2) educating the public about lifestyle related to cancer incidence and educating cancer patients about available resources and methods for coping and surviving with the disease. Examples of current initiatives are: studies of psychosocial precursors of cancer, reduction of adverse psychological reactions to cancer chemotherapy, patient education programs to reduce distress during cancer treatment, studies of differences between black and white patients with cancer of the breast, colon, bladder, and corpus.

Occupational Cancer studies are concerned with intervention research in populations at high risk of developing cancer due to occupational exposures. Current health and behavior initiatives include: education programs for chemical, coke oven, auto, rubber industry workers and painters aimed at providing such individuals with the knowledge and behavioral resources to protect themselves against increased occupational risk.

Cancer Training programs are directed at training health professionals in all the sciences relevant to the broad areas of cancer prevention and management, including the behavioral sciences.

Current initiatives include: awards to institutions in the following areas: (1) pain management including studies of its psychological parameters, cancer treatment effects upon the psychological, social and intellectual functioning of cancer patients, family and staff; (2) clinical trials of intervention strategies to reduce the psychological sequaelae of cancer; (3) knowledge and attitude as determinants of behavior relevant to cancer prevention, detection and treatment compliance; (4) relationship of psychological phenomena to immune and endocrine functions; (5) identification of factors that influence compliance with chemotherapy, radiation, and screening (6) identification of factors that influence in-hospital discomfort, uncertainty and mood disturbances and the development of interventions to improve these; (7) behavioral interventions for children with cancer; (8) biobehavioral control of chemotherapy side effects.

SMOKING, TOBACCO AND CANCER

The Smoking, Tobacco, and Cancer Program emphasizes intervention activities to reduce smoking and tobacco use prevalence, using prevention and cessation strategies. Specific audiences being targeted are school age youth, minorities, women, smokeless tobacco users and heavy smokers. Specific intervention strategies being emphasized are the role of physicians and dentists in prevention and cessation; the use of "self-help" programs for smoking cessation; the use of mass media to influence and reinforce prevention and cessation behaviors; and utilization of natural community resources (media, worksite, hospitals, churches, etc.) to identify and influence the heavy smoker to quit smoking. Internationally, the World Health Organization is working with the Institute to develop an analysis of the economic and health consequences of producing and consuming tobacco in selected countries.

Future Initiatives

Since a substantial proportion of cancer can be controlled, a reduction in cancer mortality by 50% before the end of the century is possible if current recommendations related to smoking reduction, diet changes, screening and state-of-the-art treatment are effectively applied. The NCI has set realistic objectives to be attained in these areas by the year 2000. The development and implementation of programs will include a number of health and behavioral considerations, since such factors are recognized as key variables in the promotion of health and the prevention and treatment of disease.

Future plans for behavioral initiatives in the NCI include emphasis on developing programs directed at both individuals and at systems. Future areas for behavioral initiatives may encompass the following:

(1) increased utilization of mammography and breast palpation;

(2) worksite health promotion interventions;

(3) primary care providers in health promotions;

(4) improvement of the quality of survival for recovered childhood cancer survivors;

(5) identification and reduction of obstacles for cancer patients;

(6) methods for monitoring dietary status and/or compliance;

(7) incentives for group/system behavior modification; for instance, working with the meat industry on methods for reducing fat in meats and meat products;

(8) effective techniques/incentives for private businesses/organizations to establish anti-smoking programs in their organizations;

(9) methods for reducing risk factors in large populations through intervention programs to examine health diffusion techniques in large populations.

Achievement of the Year 2000 goal of reducing cancer mortality rates by 50% will require efforts on a national scale and the participation and commitment of individuals and systems far beyond the traditional health sector including the efforts of individuals, their families, the employers for whom they work, and the communities in which they live.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

The National Heart, Lung, and Blood Institute (NHLBI) provides leadership for a national program in diseases of the heart, blood vessels, lungs and blood, and in the uses of blood and the management of blood resources.

It plans, fosters, and supports an integrated and coordinated program that includes investigations, clinical trials, and demonstration and education projects relating to the causes, diagnosis, treatment, and prevention of heart, blood vessel, lung, and blood diseases. The program also includes studies of blood resources. In addition, the Institute supports research relating to heart, blood vessel, lung, and blood diseases and transfusion medicine.

Current and Future Initiatives

Since FY 1983, increasing research emphasis has been placed on behavioral factors associated with disease prevention, etiology, diagnosis, treatment, and rehabilitation. Results of studies have demonstrated that the prevention and treatment of chronic diseases, including heart disease and stroke, benefit from multidisciplinary approaches that include behavioral medicine. National attention is being called to the need for individuals to take greater responsibility for their own health and to modify appropriately their health behavior and lifestyles. Biobehavioral approaches to the treatment of hypertension, Raynaud's disease, asthma, and coronary heart disease have also received increasing attention.

Epidemiology and Biometry

Many studies in this area provided for the collection of psychosocial data. The Framingham Life History Questionnaire, for example, has provided information on the relationships of various behavioral and psychological precursors to cardiovascular disease. An extensive psychological questionnaire is currently being administered in the Framingham Offspring Study. In addition, a major epidemiologic investigation, Longitudinal Studies of Coronary Heart Disease Risk Factors in Young Adults, contains psychosocial components, as does the NHLBI Twin Study. These large population studies provide data on various psychosocial factors in disease etiology. Analysis of the data helps to define the parameters for more detailed biobehavioral research, which is conducted in small field and laboratory settings.

In FY 1983, the NHLBI sponsored a workshop entitled "Measuring Psychosocial Variables in Epidemiological Studies of Cardiovascular Disease." Six areas were identified as important precursors to the development of cardiovascular disease: socioeconomic factors; the absence of social support; chronic life situations and life change events; type A behavior, anger and hostility, and other personality characteristics; and acute psychological reactivity.

Prevention and Education

Several educational programs are under way in schools, at work, and in various community settings that focus on the reduction of known cardiovascular disease risk factors. These efforts emphasize changing behavior to reduce morbidity and morality. The success of these programs depends on the application of knowledge from the behavioral and social sciences in such areas as attitude and behavior modification, information dissemination, education, and life skills training.

Educational efforts at the National Heart, Lung, and Blood Institute have resulted in two new national risk factor reduction programs: The National Cholesterol Education Program and the National Smoking Educational Program. These programs are modeled after the successful National High Blood Pressure Education Program.

Other educational programs are more regional in nature and are community based. The Pawtucket Heart Health Program, for example, includes the development of persuasive materials for distribution to community residents, and also of leadership and social skills training. Similarly, the Minnesota Health Heart Program and the Stanford Five-City Multifactor Reduction Study have utilized psychosocial and biobehavioral knowledge to develop successful community-wide interventions.

Several nutrition-related efforts include biobehavioral and psychosocial components. In a proposed study of obesity in young black and white females, for example, detailed information on such factors as the child's self-concept, the family environment, and social relations will provide an understanding of the variables that may influence the development of obesity in young females.

In the area of lung diseases, activities include prevention or control of respiratory diseases in various populations, in addition to psychophysiological studies of behavior and its effects on respiration, and smoking cessation counseling in comprehensive care settings, as part of obstretic care, and at work. In addition, the lung disease program supports development of education strategies for pulmonary patients and, in the case of children, their families. Several studies have focused on teaching self-management skills to asthamatic children and their parents. Other studies include amelioration of asthmatic symptoms through biofeedback, and behavior control of sleep apnea in patients with chronic respiratory disease.

Behavioral Medicine

Major areas of investigation in behavioral medicine include hypertension, coronary heart disease and atherosclerosis, and cardiac arrythmias and sudden cardiac death. Research initiatives include studies of genetic and psychosocial factors affecting smoking cessation relapse and developmental factors in the etiology of hypertension, and of biobehavioral factors affecting hypertension in blacks. Three program initiatives are under way. In the area of exercise, stress, and atherosclerosis, investigations focus on mechanisms whereby exercise may reduce the deleterious effects of stress with respect to the development of atherosclerosis. In smoking cessation for patients with recently diagnosed cardiovascular disease, scientists are exploring smoking cessation programs that take advantage of the motivational factors associated with the diagnosis of cardiovascular disease. Researchers are also investigating the mechanisms through which stress-related neuroactive peptides contribute to the development of cardiovascular disease.

NATIONAL INSTITUTE OF DENTAL RESEARCH

The National Institute of Dental Research (NIDR) is mandated to support research and training "to improve the dental health of the people of the United States." In the NIDR Long-Range Research Plan for FY 1985-1989, behavioral research is one of three special areas of research emphasis, and the others are prevention and epidemiology, which also benefit from the contributions of the social and behavioral sciences. In the context of fulfilling the NIDR's mandate, support is provided for research focusing upon behavioral, social, and cultural factors influencing the etiology, prevention, diagnosis, and treatment of dental diseases and oral conditions. Extramural research grant and training support is administered primarily through the Craniofacial Anomalies, Pain Control, and Behavioral Research Branch. During the period of FY 1983 to FY 1985, NIDR's support for research on health and behavior almost doubled from about $2.1 million to $3.9 million. Overall purposes for this support include:

> To describe, understand, and predict human behavior as it relates to oral health and disease;
>
> To develop and test behavioral interventions which promote prevention and/or treatment of oral disease and malconditions.

Current Initiatives

One major research initiative during FY 1983 and FY 1984 involved a planned expansion of prevention and treatment-related sociobehavioral research through establishment of one or more Oral Health and Behavior Research Centers. Toward this end, an RFA was published February 3, 1983, with scientific review completed early in FY 1985. Although several of these Center applications received marginally fundable priority score levels, the demand on available funds from funding in other areas for grants judged as having higher scientific merit obviated the possibility of funding such a Center. Nevertheless, the most meritorious components of these Center applications are now being re-formulated into research grant and program project applications and programmatic efforts are being made to accomplish the initial aims of this initiative utilizing these mechanisms. Such applications received during FY 1985 reflected an expanded emphasis upon sociobehavioral risk factors related to oral diseases, as well as behavioral research to increase the acceptability of dental care, and to improve compliance with therapeutic and prevention regimens. State-of-the-science reviews on major topics within behavioral dentistry were conducted during FY 1983 and were edited and published allowing for wide dissemination within the scientific community during FY 1984.

An interdisciplinary workshop titled Dental Fear and Anxiety was held September, 1985 and elicited research recommendations from pharmacologists, behavioral scientists, and dental clinicians. Resource papers and recommendations from this conference will be published during FY 1986.

In addition, a state-of-the-science review on dental social epidemiology was commissioned and completed during FY 1985.

Future Initiatives

A substantial expansion of sociobehavioral research related to oral disease prevention is planned. An RFA addressing various aspects of oral disease prevention and health promotion research will be developed as one means of stimulating expanded research efforts in this area. In addition, special efforts will be made to stimulate scientifically meritorious small business initiative grants for developing and assessing community-based disease prevention and health promotion strategies.

An expansion of research elucidating behavioral factors which influence acute and chronic orofacial pain is anticipated in FY 1987. Funding of one of the orofacial pain research center applications is currently under review. In addition to expanding research on behavioral factors influencing the perception and modulation of pain, additional efforts will be made to assess more fully potential behavioral teratogenic efforts of several pharmacological agents commonly used in dental practice, such as nitrous oxide and local dental anesthetic agents. An inter-agency agreement with the National Center for Toxicological Research will be implemented during FY 1986 and programmatic efforts will be made to supplement the score of NIDR's research grant portfolio on this topic.

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) supports a variety of neurobehavioral studies as it carries out its mandate to serve as the focal point in the Department of Health and Human Services for research on the nervous system and human communication. Much of the research NINCDS sponsors is devoted to understanding how the nervous system governs behavior. From FY 1983 to FY 1985 the NINCDS has supported a wide range of clinical and basic research in neurobehavioral topics in institutions all over the United States as well as in its intramural laboratories. Funding for research on health and behavior in this period increased from about $1.5 million to $2.1 million.

Current Initiatives

The clinical research involves many different neurological disorders. One extramural multidisciplinary project focuses on epilepsy. In addition to clinical trials of new antiepileptic drugs, scientists at this clinical research center are exploring the roles of environmental factors that provoke stress and may influence seizure frequency. Another NINCDS research project explores chronic pain and its mechanisms, how pain develops, and several potential treatments. Pain is also the topic of an investigation in which scientists are assessing the efficacy of interventions for chronic back pain. Among the treatments under consideration are 1) group cognitive therapy and relaxation training and 2) group behavior therapy with a structured exercise program.

NINCDS sponsors investigators who are developing and evaluating rehabilitation strategies for speech and auditory training for the hearing impaired. Scientists are studying neurogenic speech disorders; their investigations include perceptual, accoustic, aerodynamic, electromyographic and movement analyses. They are exploring the intelligibility of speech which is imperfectly articulated because of poor muscle control and hope to develop and refine techniques for rehabilitation of several types of motor speech disorders. NINCDS is also supporting scientists at a cerebrovascular research center. These scientists are conducting neuropsychological investigations of patients with cerebral circulatory disorders and relating these findings to regional blood flow studies of the patients' brains. The behavioral consequences of stroke are also a focus of this project.

Several other projects consider the effects of neurosurgery and of neurological disorders which affect different parts of the brain. Studies of patients who have had the corpus callosum cut to reduce their epileptic seizures--"split-brain cases"--have allowed better inferences to be made about the different functions governed by the brain's two hemispheres. This precise technique has been used to study depth perception, color vision, recognition of faces, and various features of verbal memory.

In addition to clinical research, NINCDS supports a varied program of basic research in the neuronal expression of behavior. The role of the central nervous system in regulating immune response is the focus of an NINCDS supported grant. Here, the investigators are conducting studies to establish the concept of a neurally mediated network which functions as a external control for immunologic homeostasis. Another grant uses the classical conditioning form of learning to show how the central nervous system can influence the immune system. In this project, scientists are trying to determine the most effective conditioning schedule for modifying the release of the immune mediators. They then attempt to determine whether it is possible to extinguish the conditional release of an immune mediator once the initial response has been established.

Several researchers are interested in event-related potentials (ERP), the electrical potentials recorded at the scalp while people or animals perform different types of tasks. Besides shedding light on the brain mechanisms that are essential to receiving information through the various sensory channels, this research is increasing our understanding of how the brain selects information to solve problems.

Scientists in the NINCDS Intrmural Research Program also conduct neurobehavioral research. One group is involved in a complex study of neurological development and learning patterns in vanishing isolated primitive societies; this work includes populations in Micronesia, Polynesia, New Guinea, and South America. The different populations are investigated with respect to human evolution and adaptability to high altitude, excessively wet or arid climates, variable food supply, mineral deficiencies, toxic exposures, and responses to severe diseases.

Other intramural scientists are exploring the pharmocology, biochemistry, and physiology of neurotransmitters. A goal of these projects is to determine the relationships between the neurotransmitter mechanisms and clinical manifestations of neurological disorders, and to use this knowledge to develop better pharmocological treatments for these disorders. NINCDS investigators are examining the pharmacology and cellular biology of a type of nerve cell called the peptidergic neuron. The goal of this project is to understand the regulatory mechanisms of these neurons and, through this knowledge, to develop new treatments for the injured central nervous system. During these investigations, the scientists developed the first chemical antagonist which effectively blocks the actions of the widely used street drug phencyclidine (PCP). This antagonist may be helpful in studying the roles of PCP-like chemicals that occur naturally in the nervous system. It may also be useful in treating PCP-induced psychoses and, in the future, in treating other psychoses.

Scientists in the NINCDS Intramural Research Program are also conducting position emission tomography (PET) studies of Alzheimer disease patients to explore their brain metabolism. This work demonstrated that the onset of dementia is preceded by dysfunction of a specific part of the cortex of the brain. The scientists showed that once cognitive impairment becomes evident, a marked intellectual decline accompanies relatively small decrements in cortical function.

Future Initiatives

The NINCDS will continue to support research projects in neurobehavioral research both in its own laboratories in Bethesda and in grantee institutions throughout the country. How the activities of the nervous system are manifested in behaviors and modified by hormonal and immunological networks will be a focus of concerted basic research. Clinical studies will continue to investigate the ties between specific diseases and neurobehavioral factors in such disorders as epilepsy, chronic pain, spinal cord injury, and stroke. The NINCDS will also support basic studies that apply imaging and biochemical technologies to explore how the normal nervous system controls behavior and how specific diseases affect the nervous system and its functions.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

The National Institute of Allergy and Infectious Diseases (NIAID) does not have a formal program for behavioral and social research. Occasionally, projects that the Institute funds in the infectious, allergic, or immunologic diseases have a behavioral component. For example, NIAID supported a research project on the treatment of insect sting allergy in children that included a component related to reasons for delay in seeking medical care. Behavioral research is also involved in studies of life-style factors in the acquired immunodeficiency syndrome (AIDS). During the period FY 1983-1985, the NIAID obligated approximately $600,000 annually on health and behavior topics.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

The mission of the National Institute of General Medical Sciences (NIGMS) is to support research and research training in the basic or general biomedical sciences and related natural sciences which are outside the general area of responsibility of any other Institute. The primary focus is on research studies concerned with expanding our knowledge of fundamental biological structures and processes. Consequently, NIGMS does not support research on health and behavior.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

The National Institute of Child Health and Human Development (NICHD) was "established for the conduct and support of research and training relating to maternal health, child health and human development, including research and training in the special health problems and requirements of mothers and children and the basic sciences relating to the process of human growth and development, including prenatal development" (Public Law 87-838, Section 441). The focus of this mandate is clearly on the study of human development from conception to adulthood, bringing to bear the multidisciplinary tools and perspectives of the biological, behavioral, and social sciences. In contrast to most of the other Institutes at the NIH, the NICHD is not disease-oriented, but rather seeks to understand the processes involved in normal growth and development so as to overcome disordered development and problems associated with population changes.

Research on health and behavior is supported at NICHD in several of its programs: human learning and behavior; mental retardation and developmental disabilities; endocrinology, nutrition and growth; and demographic and behavioral sciences. During the period covered by this report, the combined annual expenditures of the the programs on health and behavior research and research training increased from approximately $14 million to $18 million. As noted in Chart 1, several Program Announcements and Requests for Applications were issued, in order to stimulate research in this area.

Current Initiatives

Human Learning and Behavior

During FY 1983-1985, research and research training in five major areas related to health and behavior have been initiated and supported by the human learning and behavior program of NICHD: (1) behavioral pediatrics, (2) developmental behavioral biology, (3) learning and cognition, (4) communication, and (5) social and affective development.

(1) Behavioral pediatrics. This research integrates the behavioral and biomedical sciences in addressing etiology, treatment, management and prevention of disease and promotion of health. Individual research projects deal with such problems as compliance with treatment of chronic diseases such as juvenile diabetes and asthma, the prevention of injury in children, the development of health-promoting and disease-preventing lifestyles and behaviors (e.g., healthy diets, exercise, avoidance of smoking and alcohol abuse), eating disorders (anorexia, bulimia), and childhood behavior problems (e.g., hyperactivity).

(2) Developmental behavioral biology. This research is concerned with the biological basis of behavior. The concepts and tools of neurobiology, pharmacology, genetics and endocrinology are used by psychobiologists to gain an understanding of the interaction between "nature and nurture" and their relative contributions to a given behavioral pattern. Data from these interdisciplinary studies are of significance for clinical interventions in disease processes related to lifestyle. To encourage these studies, a program announcement was issued in FY 1983 for individual fellowships and institutional training grants in this interdisciplinary field.

(3) Learning and cognition. This research is concerned with the acquisition of social skills, language mastery, self-management, and compliance with instructions, inattention, disruptive behavior, self-injury, hyperactivity and withdrawal in both children and adults. Currently, active projects seek to understand the processes by which children acquire knowledge, learn to think, solve problems (i.e., behave creatively), and remember and apply knowledge. Investigators are studying how and when infants and children perceive and organize their sensory world, and the differences and similarities between adult and child perception. Applications of this research include assessing the developmental

and neurological status of premature babies and others at risk for impaired development.

(4) Communication. NICHD supports research on speech and language development, both normal and impaired. Dyslexia is a major concern, as is language acquisition in special populations, such as the hearing-impaired.

(5) Social and affective development. This category includes projects on the emotional development of the infant and child, prosocial behavior, aggression, and social awareness as these are manifested in the family, the peer group, and in the larger community setting.

Mental Retardation and Developmental Disabilities

During FY 1983-1985, research and training have been supported on topics related to behavior relevant to health by the mental retardation and developmental disabilities program of NICHD. Some of these topics are:

(1) Behavior-analytic studies which attempt, through manipulation of the interactions between behavior and environment of mental retardation and developmental disabilities (MRDD) individuals, to bring about a reduction of behavior problems, to facilitate vocational training and learning, and to increase social and self-help skills.

(2) Research on family and community processes, including studies on effects of children with MRDD on family life; family and community factors influencing healthy developmental outcomes and adjustments; organization and use of community resources; use of social support networks; parent-child interactions and family interactions.

(3) Research on early diagnosis and intervention, which has demonstrated the effectiveness of early infant stimulation and intervention programs in improving health and performance of MRDD individuals and suggested that a child's progress is a product of both the capacities and the experience of the individual.

(4) The development of language and communication skills among MRDD populations.

Endocrinology, Nutrition, and Growth

During FY 1983-1985, research in four areas related to health and behavior has been supported by the endocrinology, nutrition, and growth program:

(1) The psychosocial aspects of obesity, including past environmental factors in childhood obesity, behavioral intervention to prevent or ameliorate obesity, and the effects of parent weight on weight of young children.

(2) Infant nutrition, with an emphasis on breast-feeding, including the demonstration of the benefit to health outcomes for children, and psychosocial factors influencing the decision to breast- or bottle-feed.

(3) Development of ingestive behavior, including the development of dietary patterns (e.g., food faddism, over- and undernutrition) and their effects on health.

(4) The effects on behavior of malnutrition, including the effects of protein-calorie malnutrition, specific nutrient deficiencies, and idiosyncratic reactions to nutrients, on social, psychological, and learning performance.

Demographic and Behavioral Sciences

During FY 1983-1985, research and training in six major areas related to health and behavior have been initiated and supported by the demographic and behavioral sciences program of NICHD: (1) determinants and consequences of fertility, (2) fertility regulation, (3) adolescent fertility, (4) mortality, (5) family dynamics, and (6) population movement and change.

(1) Research on the determinants and consequences of fertility deals with the effects of fertility on the health and well-being of sexual partners. Health problems occurring during pregnancy are studies in relation to their social and economic as well as physical effects on outcomes.

(2) Fertility regulation may have direct health effects on both parents as well as the offspring. Issues of contraceptive behavior (e.g., choice, use, and compliance) are studied.

(3) Research on adolescent fertility receives special emphasis because adolescent childbearing and fertility regulating behavior exacerbate the nature and extent of the health and health-related problems encountered. The physical, psychosocial, and emotional immaturity of adolescents with respect to childbearing and parenting has profound implications for the health of both the parent and the child. Also, adolescents seem to be at higher risk of maternal morbidity and mortality than adults. The health, cognitive development, emotional development, and school achievement of the children of adolescent mothers have also been shown to be adversely affected.

(4) Research on mortality is concerned with collecting data on mortality across many demographic variables and provides the basis for understanding and trying to improve individual and public health.

(5) Research on family dynamics (i.e., family constellation and interaction) has demonstrated an effect on the health of both parents and children. The study of single-headed families, families disrupted by separation or divorce, and extended families yields insight into the health effects and health-related behaviors of these different family constellations.

(6) Research on population movement and change demonstrates that health and health-related behaviors are affected by such variables as population density and shifts. Availability of health care services may be altered by population movement, and the composition of populations, such as mix of racial and ethnic groups, can also influence living conditions and health behaviors.

Future Initiatives

Human Learning and Behavior

NICHD plans to continue pursuing the research directions in each of the five areas discussed earlier. In addition, increased emphasis will be placed upon specific topics within these areas.

(1) In behavioral pediatrics, research on prevention of childhood injuries, improved methods of infant assessment, compliance with health regimens and instructions, and health-promotional activities will be encouraged.

(2) In the area of developmental behavioral biology, research will be solicited that links the fields of genetics, neurobiology, endocrinology, and pharmacology with behavior. Genetic studies of learning disabilities will be particularly encouraged.

(3) Learning and cognitive research will stress perceptual development, cognitive measures of developmental deficits, development of habituation, cognitive assessment measures and longitudinal measurement of cognitive development, and cross-modal perception. One goal of this research is early identification of developmental delay to permit early interventions.

(4) In the area of communication, additional studies will be encouraged in speech and language development, reading and dyslexia, and non-human primate communication as a model for understanding development of communicative abilities and disabilities in children.

(5) In addition to the current research on social and affective development, studies on the impact of family change (single parent, divorce, both parents employed) and extrafamilial influences on children's behavioral development will be encouraged.

Mental Retardation and Developmental Disabilities

NICHD will continue to pursue the research directions described earlier with an emphasis placed on filling some critical gaps in knowledge that have been identified by the scientific community.

(1) In the area of behavior analysis, efforts will be concentrated on a) determining the maximum extent of behavior change possible in MRDD individuals, employing known operant conditioning principles over extended periods of time; b) the best methods to integrate behavior-analytic approaches with biomedical and psychological methods; and c) the application of behavior analysis to a broader range of health and behavioral problems of the handicapped than heretofore.

(2) Research on family and community processes will stress information on functioning over the life span of mentally retarded persons. The aging or elderly members of this population are virtually unstudied, and knowledge of cultural, regional, and social class differences in health status and the development of social competence and achievement of life satisfaction are needed. The achievement of competence and the processes conducive to it and to achieving residence in the least restrictive environment will be investigated.

(3) In the area of early diagnosis and intervention, research will focus on determining the most effective interventions and the ages at which they are most critical for achieving maximum benefit in limiting or preventing MRDD.

(4) Research on language and communication in the retarded has demonstrated that language training may be the most effective system for making significant alterations in the course of their development. Therefore, NICHD will encourage and support studies to derive measures of language which have predictive validity for educational achievement in retarded individuals, and to determine the relationship between earlier and later language skills. This will be coupled with systematic investigations of the role of a given environment in exacerbating or ameliorating language learning problems for various at-risk populations.

Endocrinology, Nutrition, and Growth

Within the endocrinology, nutrition, and growth program, NICHD intends a variety of activities:

(1) A conference on psychosocial origins of *obesity* will be held in order to discuss research needs and opportunities for identifying further psychosocial factors lending themselves to behavioral intervention.

(2) In the area of *infant nutrition*, studies will be continued to identify social and behavioral factors which might be modifiable in order to improve the nutritional status of pregnant and lactating women (particularly among socio-economically deprived populations) with the goal of reducing infant mortality and morbidity.

(3) Studies of the *development of ingestive behavior* will emphasize identifying parental and family components in the development of dietary patterns. Research on compliance with nutritional regimens, as for example in children with diabetes, will also be supported.

(4) In the area of *effects on behavior of malnutrition*, research on the effects of deficiencies of iron and micronutrients on cognitive functioning will be emphasized.

Demographic and Behavioral Sciences

(1) In regard to the *determinants and consequences of fertility*, research will stress analyses of the interacting factors contributing to continual and effective use of methods of fertility regulation. Studies of motivational and decision-making processes influencing the selection and continuation of use of fertility-regulating methods will be supported. NICHD plans to encourage research on such matters as the influence of health issues (e.g., side effects) on fertility decisions, especially with regard to delayed childbearing, and the consequences of sexually transmitted diseases on decisions concerning contraceptives.

(2) Special attention will be paid to understanding the *fertility regulating* behavior of both men and women, of couples and of other selected groups. Choice, effectiveness, and continuation of use of fertility-regulating methods will continue to be studies, as well as the acceptability and utilization of proposed new methods of fertility regulation.

(3) NICHD will emphasize basic research on the behavioral factors related to or determining *adolescent fertility* and unplanned

pregnancies. More studies will be undertaken on the effects of adolescent childbearing on the health and psychosocial development and well-being of both parents and their offspring.

(4) The major emphasis in the area of mortality will be infant mortality, particularly the continuing disparities among racial and ethnic groups. There are strong indications that social and behavioral processes, including the pattern of childbearing, influence the risk of adverse pregnancy outcome or infant mortality and contribute to the explanation of differences among groups.

(5) Concerning family dynamics, major initiatives will continue to stress the effects of childbearing patterns, marital disruption, changes in family and household composition, and other life transitions on the the health and development of children and their families. The relationship of child care arrangements to the health of the child and of other family members will be emphasized.

(6) There will be a continuing focus on those aspects of population movement and change which related most directly to health and health behaviors. The manner in which immigrants adjust to the conditions they find in the United States as they impact on their health and well-being will be investigated, as will the impact the immigrants themselves have on the health and growth of the communities in which they live.

NATIONAL EYE INSTITUTE

In the area of health and behavior, the National Eye Institute (NEI) is supporting a study of patient compliance with topical (eye drop) ophthalmic therapy. Previous studies have indicated that many outpatients do not utilize their medications properly. Poor patient compliance has a substantial impact on disease prognosis, response to treatment, and economic cost to both the patient and society. In this study, compliance is being assessed in patients who have been prescribed the drug pilocarpine to control the ocular hypertension of glaucoma. A specially designed eye drop medication monitor which electronically records the day and time of each medication administration is being used to evaluate and to determine the overall effect of compliance on the prognosis of patients with primary open-angle glaucoma. The effect of various interventions on the improvement of patient compliance (written pamphlets, discussion with the physician, use of a patient diary of pilocarpine administration) is also being evaluated.

Compliance with the treatment regimen is being determined in the same manner for other topical ophthalmic medications in selected acute and chronic ocular conditions.

In response to a request from the Senate Committee on Appropriations, the NEI prepared a report in March 1985 on the possibilities and cost of a glaucoma control research initiative. One of the recommendations in that report is to encourage laboratory and clinical research in scientific areas that are likely to help in reducing the occurrence of blindness in glaucoma. This includes studies of the reasons for patient noncompliance with medical advice and development of methods for increasing motivation to comply with medical advice in glaucoma.

The midcourse evaluation of NEI's five-year national plan for vision research, which was conducted during FY 1985, also addressed the issue of compliance by designating the study of patient compliance with drug regimens prescribed for treatment of primary open-angle glaucoma as a Program Development Priority.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

The National Institute of Environmental Health Sciences (NIEHS) supports research on behavior as a component of studies on the behavioral and neurological effects produced by toxic substances. Special emphasis is placed upon the changes in behavior and neurologic function produced by long-term exposure to low levels of a wide variety of chemical and physical agents present in the environment, as well as to exposure during development of the nervous system. The goal of NIEHS behavioral research is to understand the functional integration of the nervous system and how environmental agents may interfere with this integration through existing mechanisms that permit normal plasticity and adaptation. Examination of behavioral and neural function following exposure to environmental agents frequently reveals the extent and nature of subtle structural or functional damage that may be present in the absence of obvious toxicological endpoints.

During FY 1983-1985, the NIEHS provided support for a single research project grant concerned with behavioral research. The goal of that project is to delineate psychological factors associated with asbestos exposure and the associated risk of development of mesothelioma.

NATIONAL INSTITUTE ON AGING

A key component in the mission of the National Institute on Aging (NIA) is to stimulate and support research and research training on health and behavior. In fulfilling its mandate to "conduct and support biomedical, social, and behavioral research and training related to the aging process and the diseases and other special problems and needs of the aged," the NIA recognizes the critical role played by social and behavioral factors in health and effective functioning as people age. Detailing the NIA's research emphases on Health and Effective Functioning in the Middle and Later Years, a Program Announcement with this title was first issued in 1981 and reissued in 1983. The thematic questions here are: How can the relatively vigorous health, effective functioning, and productivity of the middle years be continued into the later years? How can disability and dependency be postponed until the last years of the life course? NIA-supported research has been suggesting answers to these critical questions. For example, we know that intellectual decline with aging (when it occurs) can often be slowed or reversed by relatively simple training interventions; that illness can often be alleviated through social supports and improved coping behaviors; that many serious disabilities (even when experienced in nursing homes) can be influenced by regimens that reward activity and independence; and that for visual impairments suffered by many older people, particular styles and sizes of type can facilitate reading and improved environmental design can offset inability to see large objects. While death is inevitable, we know in a most general sense that biological, psychological, and social processes of growing old are to a considerable extent malleable. However, continuing research is needed to specify the mechanisms and conditions that influence health and effective functioning during the middle and later years.

Behavioral and social research on health and effective functioning is supported mainly through the NIA's extramural research programs, especially the Behavioral Sciences Research program. (Some extramural research is funded through the Biomedical Research and Clinical Medicine program.) The NIA's intramural program at the Gerontological Research Center in Baltimore, Maryland, also conducts some behavioral research relevant to health and effective functioning. Extramural and intramural research on health and effective functioning at the has more than doubled from about 5.2 million to 12.8 million dollars over this period. (See Table 1.)

Current Initiatives

Building upon general efforts begun in 1981 to understand the complex relationships among human behavior patterns, effective functioning, and health, NIA extramural and intramural research initiatives in FY 1983-1985 have emphasized four specific areas: 1) behavioral geriatrics research 2) cognitive, intellectual, and sensorimotor functioning, 3) social and environmental interventions to promote and maintain health and effective functioning, and 4) the functioning and health of the "oldest old." Research under these initiatives includes such topics as behavioral interventions for preventing and treating age-related declines in cognitive functioning, attitudinal studies of symptom recognition by the elderly, and large-scale survey investigations of social and behavioral risk factors in older adults.

These four specific areas where basic research on mechanisms and conditions have been encouraged by the NIA over the past three fiscal years are described as follows.

Behavioral Geriatrics Research

A variety of studies in the United States and other countries has demonstrated the importance of social and behavioral factors in the causes, prevention, diagnosis, treatment, and recovery from illness in later life, as well as in the maintenance of health over the life course. An often-quoted report from the Surgeon General states that society will achieve its health goals primarily through changes in behavior. In order to specify such a global statement, the NIA issued two program announcements in 1983 encouraging the development of behavioral geriatrics research as a new area in behavioral medicine. Behavioral geriatrics research is concerned with a) the origins, nature, and malleability of health-related attitudes and behaviors of old people and health-care providers, including beliefs about the nature of the aging process, b) "illness behaviors" such as how older individuals monitor their bodily functioning, what determines whether and what kinds of remedial actions they take, and whether they follow prescribed regimens, c) cohort and longitudinal studies on the effects of "life-style" (e.g., nutrition, exercise, smoking), personality (e.g., stability and significance of the components of Type A behavior patterns), and "life stresses" (e.g., retirement, bereavement, daily hassles) on morbidity and mortality, d) the role of informal care provided by family, friends, and neighbors, vs. formal care by organized health services and specially trained practitioners, e) the design and evaluation of behavioral therapies as alternatives to surgical or pharmacological treatments (e.g., a Request for Applications was issued in 1984 to support clinical trials for behavioral therapies of urinary incontinence), and f) the specification of physiological processes intervening between social and behavioral factors, on the one hand, and health outcomes on the other.

Cognitive and Intellectual Functioning

Intellectual functioning, memory, perception, and psychomotor skills are central to the maintaining effective functioning and health as people age. NIA-supported research has demonstrated that, contrary to conventional wisdom, few healthy individuals up to age 60, and less than half even at age 80, show reliable aging decrements in cognitive test performance. Given training and incentives, elderly people can learn to perform as well on tests as people 20 years younger than they. An even more basic finding is that deficits in reaction time can often be remedied. Thus, cognitive and intellectual functioning are proving to be widely variable and extremely malleable across domains and individuals. Current research is focusing on identifying aspects of functioning that change or remain stable and on specifying the biological, psychological, and social processes influencing intellectual and cognitive functioning.

Laboratory research has demonstrated age-related differences and changes in visual functions as acuity, dark/light adaptation, contrast sensitivity, or color perception. But, further studies are needed on visual perception: on how visual signals and information are interpreted and responded to in later life. For example, NIA-supported research has shown that the standard eye chart may be a good measure of visual acuity in the elderly under idealized conditions of the laboratory or the doctor's office. However, having passed such a test, an elderly person may fail to see as large an object as a truck under certain lighting conditions. Thus, visual perception should be scrutinized in the light of older people's experiences and expectations and within the contexts of their everyday lives at work, in the household, and in the community. Moreover, in explaining differences among similarly impaired individuals performing "real world" visual tasks, motivational differences and cognitive factors need to be taken into account. In order to stimulate research along these lines, the NIA issued a Program Announcement on Aging and Visual Perception in 1983.

Social and Environmental Interventions

The social and behavioral sciences show that aging is not entirely immutable, but consists of highly variable social and psychological as well as biological processes. For some people aging means healthy, effective, fulfilling lives, while for others aging means chronic ill health, prolonged disability, loneliness, and disengagement from affairs. Such differences in the ways people age are influenced not only by biology, but also by the social environments in which they lead their daily lives -- by the work they do, the people they interact with, the household and community in which they live. Via another Program Announcement issued in 1983, the NIA is encouraging research projects designed to identify specific modifications of these immediate social environments that may improve the health and effective functioning of middle-aged and older persons. For example, how can jobs be modified to maintain or even improve intellectual and cognitive functioning, productivity, and health of older workers? How can special assistance from family and neighbors be arranged to maintain independent functioning in the home in order to prevent or postpone institutionalization? How can daily regimens, even in nursing homes, be established to maintain or restore activity, personal control, and well-being of elderly patients?

Health and Functioning of The Oldest Old

The oldest old (those over 85 years of age) are the fastest growing segment of the population and they are very substantial users of health care and other services. While about six percent of those aged 75-84 are institutionalized, the rate for those over age 85 is about 23 percent. Among the non-institutionalized elderly, the need for help in one or more activities of daily living increases substantially with advancing age (16 percent for those 75-84 vs. 40 percent for those 85 and older). The Federal Government provides, by some estimates, $51 billion annually in major benefits to those 80 and over. Thus, if the current health care utilization rates are extrapolated simply as a function of the projected growth in size of the oldest old population, then the implications for society are considerable. Yet, at almost all levels, from the demographic to the physiologic, less is known about this age group than about any other.

At the end of 1984, the NIA published a program announcement calling for research to provide basic information about the oldest old. Among other topics, the announcement encouraged a) socio-demographic studies of their distribution and projected growth by, e.g., sex, race, education, income, residence, and living arrangements and proximity of surviving kin; b) analyses of stability and decline in such abilities as memory and problem solving; c) clinical, pathologic, and epidemiological investigations of the prevalence, course, morbidity, and mortality of diseases as well as of the interactions among multiple disease processes; d) research on physiologic factors (e.g., metabolic, endocrine, immune) which increase or diminish risk for decrements in functioning, specific diseases, and mortality from disease; e) studies of the care systems for the oldest old such as the impact of the changing family and increasing participation of women in the labor force on the provision of care for future cohorts of the oldest old; and f) inquiries into factors affecting institutionalization of and the use of services by the oldest old.

Future Initiatives

The NIA anticipates continuing to support health and behavior research and training along the existing substantive lines and at approximately the same fiscal level during FY 1986 and FY 1987. Rather than expand the program to include more topics, and thereby diffuse its efforts, the NIA believes it more appropriate to reinforce and consolidate its existing research emphases that are now coming to fruition. For example, the following activities are in various stages of planning and implementation:

Release of a Request for Applications in FY 1987 calling for research on the complex interrelationships among immune functioning, stressful events, coping styles, social support, and health.

Issuance of a Request for Applications in FY 1987 soliciting research on improving methods for forecasting the health and active life expectancy of the oldest old population.

Publication of papers commissioned as part of a previous workshop on Cognitive and Intellectual Functioning for the purpose of stimulating research. Newer studies are sought on components of intellectual functioning that are not currently measured in standard tests, that draw upon experience, and that may develop or improve in middle or later life.

Publication of papers from a previous workshop on the health care for the elderly from the perspective of the social sciences. These papers identify areas where additional research is needed.

Publication of papers from the June, 1985 Conference on Forecasting Life Expectancy and Active Life Expectancy for the Oldest Old.

Through interagency agreements with the U.S. Bureau of the Census and the National Center for Health Statistics, several data sets that will provide more detailed information on the older population are being prepared for use by extramural and intramural scientists. In some instances, this involves reformating existing data to make them more amenable to research on health and behavior among the elderly, and in other instances, it involves the collection of new data.

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

The psychological factors that influence the development, treatment, and prevention of a given disease are profoundly important to a basic understanding of the nature of that disease. The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) has a continuing interest in pursuing research that takes full advantage of the knowledge to be gained from the behavioral sciences in order to improve the management and control of the wide spectrum of chronic and disabling diseases for which the Institute is responsible. The Institute's expenditures on such research increased from $5.1 million in FY 1983 to $6.5 million in FY 1985.

Current and Future Initiatives

Often for such diseases, the critical problem facing health care providers is not one of choosing an appropriate medication or other treatment regimen but of obtaining the patient's cooperation with the required preventive or therapeutic program. For example, all people with diabetes must restrict or alter their lifestyles because of dietary changes and the necessity for a closely regulated time schedule for meals and exercise and, if required, insulin injections. This life-long regimen poses special psychosocial and behavioral concerns, especially when children are involved. The Institute has funded a number of studies to develop optimal strategies for improving behavioral compliance as well as to determine relationships between psychological stress and fluctuations in the course of diabetes. Findings suggest that events generating anxiety, specific intrapsychic conflicts, emotional deprivations, conscious and unconscious threats to security, and actual unpleasant psychological experiences may upset diabetic control.

Arthritis and musculoskeletal diseases also pose challenges of long-term management, as well as control of pain and other debilitating symptoms. In one study, researchers are comparing the effectiveness of relaxation and biofeedback strategies versus cognitive training on pain control in patients with rheumatoid arthritis. Other studies seek to identify the variables associated with effective arthritis self-management behavior and improved health outcomes. Efforts are also ongoing to help prevent the development of osteoporosis by modifying individual lifestyles; these efforts advocate increased ingestion of calcium and regular performance of weight-bearing exercise. Studies are also being conducted to assess the effects of life stress and social support on the quality of life, functional level, and compliance with treatment regimens of patients with osteoarthritis.

In digestive diseases, fully half of all referrals to gastroenterologists are for symptoms usually presumed to be of a functional origin (i.e., a psychological basis). To deal with this situation as well as the exacerbation of many digestive diseases that occur through reactions to stress, the Institute recognizes the need to arrive at a better understanding of the relationship between psychological responses and processes and the neurohormonal control of gastrointestinal functions, including motility, transport, and such phenomena as vomiting and diarrhea.

An estimated 30 million adult Americans are believed to suffer from obesity, a condition correlated with significant health risks. Examination of behavior in this population is important since attitudes toward foods and dieting can influence the desire for food, food choices, exercise, and activity profiles. While obesity may follow family lines, it is not clear what the major predisposing factors are. Early nutrition behaviors, taste responsiveness, and family eating and activity profiles are all critical areas of investigation. A related area of emphasis involves behavioral and social research on eating disorders, such as bulimia and anorexia nervosa.

Ongoing Institute research in the area of kidney diseases is focused on the longitudinal effects of end-stage renal disease (ESRD) on the neuropsychological functions of children and adolescents. Specifically, researchers are examining the behavioral and psychosocial effects of the institution of different forms of dialysis or of kidney transplantation as modes of therapy for ESRD.

DIVISION OF RESEARCH RESOURCES

The Division of Research Resources (DRR) establishes multidisciplinary resources or centers to facilitate the efficient and effective conduct of biomedical and behavioral research. The Division awards Minority Biomedical Research Support Grants to increase the participation of ethnic minorities in the biomedical sciences; Biomedical Research Support Grants to enhance the effectiveness of research institutions receiving PHS grant support; and Shared Instrumentation Grants for the acquisition and updating of expensive shared-use instruments. Preliminary assessment of the latest basic research discoveries regarding the safety and efficacy of new research techniques or modes of therapy occurs in Primate Research Centers and further assessment of these new therapies occurs in General Clinical Research Centers (GCRC) prior to their use in health care settings. Through these resources, DRR supports the full range of health and behavior research funded by the NIH. The following are selected examples.

Current and Future Initiatives

Animal Resources Program

Behavioral Side Effects of Antipsychotic Drugs. About 10 to 15 percent of the patients who undergo long-term treatment with antipsychotic drugs develop a cluster of symptoms called tardive dyskinesis (TD). The most common symptoms are involuntary repetitive movements of the tongue, mouth, and face which are troubling and may hinder the social adjustment of outpatients. Data from animal studies, using the capuchin (Cebus) monkey model of neuroleptic-induced TD at the Oregon Regional Primate Research Center (ORPRC), are compared to the results of clinical research at the Veterans Administrative Medical Center and Oregon Health Sciences University.

Neuroleptic drugs block the action of dopamine, a primary neurotransmitter in the brain by binding to the dopamine receptors of nerve cells. Reducing the activity of this neurotransmitter, which has been linked to many mental disorders, alleviates the delusions that cause psychotic behavior. Many researchers believe that the central nervous system of some patients adapt to longterm therapy by increasing the number of specific dopamine binding sites which results in dopamine receptor hypersensitivity. This may correlate with the subsequent appearance of tardive dyskinesia. Researchers have tried to achieve a satisfactory balance between the two side effects, lowering dosage to a level that minimizes movement disorders yet controls psychoses. The fact that psychoses can be controlled at the same time TD symptoms are reduced suggests that a drug more specifically affecting the mechanism of psychoses might not cause movement disorders.

General Clinical Research Centers Program

Side Effects of Lithium Therapy. Researchers at the University of Chicago GCRC are finding that the excessive drinking and urination often seen in manic depressive patients treated with lithium is caused by more than one mechanism. In about half the patients these side effects are caused by a failure of the kidney to respond normally to the antidiuretic hormone vasopressin. In the other half of the patients the effect seem to result from excessive drinking. Together with the earlier findings that lithium increases vasopressin secretion, these findings indicate complex effects of lithium on water metabolism. They have important practical implications for the therapy of lithium treated patients.

Hyperactive Behavior in Children. Investigators at the University of Iowa Hospitals in Iowa City are studying the role of refined sugar in exacerbating hyperactive behavior in children. This problem has received considerable attention in the popular literature. In recent GCRC studies a challenge design was used to investigate the effects of sucrose ingestion after an overnight fast or after meals on the behavior and learning of hyperactive boys. Behavioral (playroom observations and examiner ratings) and cognitive (learning and memory tasks) measures made after the challenges revealed no effect of sugar ingestion on the boys' performances. The findings make it appear to be unlikely that sucrose plays a major role in aggravating the inappropriate behavior of hyperactive boys.

Eating Behavior. Despite the extensive investigations of obesity that have carried out for many years, very little is known about the role that individual eating behavior plays in this condition. Currently available methods to record eating behavior are cumbersome and probably unreliable over extended periods of time, and they are subject to significant observer bias. Newly developed intraoral sensor devices have recently been found to provide an unobtrusive and accurate method for recording chewing and swallowing during a meal. Subjects can be studied while eating liquid meals as well as solid food units designed especially for these studies. Detailed and accurate records of oral events associated with eating have been obtained, and programs for digital conversion of the data for computer analysis have been developed. Researchers at the University of Pennsylvania GCRC expect this device to provide objective data on eating behavior in obesity and other eating disorders.

Biomedical Research Support Program

Aerobic Exercise and Neuropsychological Function in the Elderly. Regular aerobic exercise improved the memory and mental dexterity of elderly subjects participating in research conducted at the Veterans Administration Medical Center and the University of Utah in Salt Lake City. Participants in a 4 month aerobic exercise program scored significantly higher in tests of mental as well as physical abilities than control groups who exercised moderately or not at all. Since oxygen is necessary for the syntheis of neurotransmitters crucial for a variety of mental functions, increased levels of oxygen in the brain might enhance an elderly person's mental capacity.

Scale Helps Classify Thought Disorder in Psychiatric Patients. In their quest to identify the primary mental defects caused by schizophrenia, researchers have long sought a reliable method for classifying the disordered thought processes of patients suffering from this devastating psychiatric illness. Researchers at University of Iowa College of Medicine in Iowa City have developed a scale to rate different types of communication behavior. In studies using the Scale for the Assessment of Thought, Language, and Communication, New York researchers found that the new method allowed them to distinguish between victims of schizophrenia and mania, psychoses with similar symptoms but different treatments. The ability to classify psychotic patients on the basis of thought disorder allows scientists to address psychological defects that lead to differences among diagnostic groups and to examine whether particular features of thought disorder respond to various treatments.

Minority Biomedical Research Support Program

Effects of Diet and Exercise. Women who exercise and cut calories can reduce risk factors for heart disease while losing more pounds than women who only diet, according to investigators at Lincoln University in Jefferson City, Missouri. Although people have taken for granted that exercise is beneficial to health, few studies have been conducted to back up that assertion. Using behavioral psychology, exercise physiology and nutrition in a series of studies, investigators evaluated the health benefits of different approaches to weight reduction. They found that women in the diet-exercise program decreased their heart rate, lowered triglyceride levels, fared better in a standardized stress test and lost twice as much weight as the women who only dieted.

FOGARTY INTERNATIONAL CENTER

The Fogarty International Center (FIC) is the focal point for NIH international research programs and is responsible for facilitating and promoting NIH involvement in international research collaboration and research training through formal and informal cooperative mechanisms. FIC's programs provide opportunities for health and behavior research through fellowship programs to U.S. and foreign scientists, scientific exchanges, and conferences that foster information exchange and scientist-to-scientist communication.

Table 1

HEALTH AND BEHAVIOR RESEARCH AND TRAINING[1] SUPPORTED BY THE EXTRAMURAL AND INTRAMURAL RESEARCH PROGRAMS OF THE NATIONAL INSTITUTES OF HEALTH

(In Thousands of Dollars)

B/I/D[2]	FISCAL YEARS 1983	1984	1985
NCI	9,317	18,789	22,608
NHLBI	17,427	19,808	25,774
NIDR	2,086	3,659	3,912
NINCDS	1,539	1,848	2,137
NIAID	527	628	651
NIGMS	0	0	0
NICHD	13,797	16,844	18,267
NEI	112	115	98
NIEHS	37	133	141
NIA	5,199	8,759	12,778
NIADDK	5,151	5,700	6,517
DRR	11,049	10,137	12,281
FIC	18	27	111
TOTAL:	66,259	86,447	105,275

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[1] See p. 4 for statement describing health and behavior research at NIH.

[2] NIH Bureau, Division, or Institute. See Table of Contents for listing of B/I/D names and abbreviations.

Chart I

Health and Behavior Research and Training Program Announcements, Requests for Applications, and Requests for Proposals Issued by the National Institutes of Health Fiscal Years 1983, 1984, and 1985

NATIONAL INSTITUTE ON AGING

Health and Effective Functioning in the Middle and Later Years,
Health Behaviors and Aging: Behavioral Geriatrics Research
Special Emphasis Research Career Award for Social and Behavioral Scientists in Behavioral Geriatrics Research
Social Environments Influencing Health and Effective Functioning in the Middle and Later Years
Aging and Visual Perception
The Oldest Old
Clinical Trials of Behavioral Therapies for Urinary Incontinence in the Elderly

NATIONAL CANCER INSTITUTE

Prevention Program

Phase III Trial of a Low Fat Diet in Women with Stage II Breast Cancer
Phase III Trial of a Low Fat Diet in Women with Increased Risk for Breast Cancer
Core Grants for Clinical Research Units
The Modification of Eating Behavior and Cancer Prevention
Studies on Obesity

Centers and Community Oncology Program

Community Hospital Oncology Program
Community Clinical Oncology Program
Cooperative Group Outreach Programs
Hospital Tumor Boards Data Set
Patterns of Care for the Elderly
Continuing Care Research: Identifying and Reducing Obstacles for Cancer Patients

Cancer Control Science Program

Cancer Control Research Units
Cancer Control Science Program
Prevention Interventions in Black Populations
Avoidable Mortality in Black Populations
Reduction in Avoidable Mortality from Cancer
Small Grants Research Program
Cancer Communications System

Cancer Patient Compliance with Therapeutic Regimens
Occupational Settings
Epidemiologic Study of Black/White Differences in Cancer Patient Survival

Smoking, Tobacco, and Cancer Program

Smoking Prevention and Cessation in the Black Population
Smoking Prevention and Cessation in Hispanic Populations
Smoking Prevention and Cessation among Women
Prevention and Cessation of Smokeless Tobacco Use
Community Intervention Studies of Heavy Smokers
Development Evaluation of Smoking Prevention/Cessation - Mass Media
Longitudinal Evaluation of School-Based Prevention - Smoking
Self-help Strategies in Smoking Cessation
Evaluation of Physician/Dentist Smoking Interventions

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Behavioral Adaptations to the Changing Structure of the American Family and Household
Antecedents and Consequences of Voluntary Contraceptive Sterilization
Research on the Nature and Extent of Out-of-Wedlock Births
The Causes and Consequences of Changes in Family and Household Structure
Consequences of Pregnancy Losses for Adolescents
Research on the Quality of Extant Data on Out-of-Wedlock Births
Research on the Relationship between Sexually Transmitted Diseases and Fertility-Related Behavior
Child-care, Fertility, and Female Labor Force Participation
Acceptability and Utilization of the Contraceptive Sponge
Effects of Contextual Factors on Fertility Regulation and on Fertility
Consequences of Infertility and Fertility-Related Problems

NATIONAL INSTITUTE OF DENTAL RESEARCH

Oral Health and Behavior Research Centers
Orofacial Pain Research Centers

NATIONAL HEART, LUNG AND BLOOD INSTITUTE

Biobehavioral Factors Affecting Hypertension in Blacks
Demonstration and Education Research on Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources
Childhood Nutrition, Physical Activity, and CV Health
Exercise, Stress, and Atherosclerosis

Smoking Cessation in Patients with Cardiovascular Disease
Behavioral Stress, Neuroactive Peptides, and Cardiovascular Disease
Workplace D&E Research in Cardiovascular Disease
Research in Nutrition and Cardiovascular Disease

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

Research Grants in the Field of Local Neuronal Interactions
Research Grants in the Integration of Autonomic and Somatic Divisions of the Nervous System
Research Grants in the Neurophysiology of Cognitive Processes
Research Grants in the Field of Nervous System Modulation of Immune Responses and Interactions between Nervous and Immune System

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Alcohol, Drug Abuse, and Mental Health Administration

Report on Services to the Elderly in Community Mental Health Programs

Robert L. Trachtenberg
Acting Administrator, ADAMHA

February, 1981

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute of Mental Health

Services to the Elderly in Community Mental Health Programs

The 1986 report of the House Appropriations Committee (No. 99-289, dated 9/26/85, page 81 makes the following statement:

> "The Committee is concerned that the Community Mental Health Centers program, which is partially funded by block grant funds, has not responded adequately to the mental health problems of the elderly. This problem is increasingly important as the American population ages. One difficulty in studying this problem is the lack of dependable data on numbers of elderly receiving treatment at centers. The Committee considers the collection of data in this area to be critical and directs the National Institute of Mental health to report back to the Committee what information is currently available and alternatives for improving our knowledge in this area. The report should be submitted prior to hearings on the FY 1987 budget."

This report is submitted in response to the Committee's request.

Available data clearly indicate that the elderly are underrepresented in Community Mental Health Centers and other community mental health programs. A 1982 General Accounting Office (GAO) study found that "Experts agree that the incidence of mental health problems among older persons is higher than that of the general population." 1/ Yet it was found by the GAO study and verified by a 1984 NIMH survey and other data reported on below that persons over age 65 continue to make up a far smaller percentage of community mental health program caseload than their numbers would suggest.

Current Data Collections

The Survey and Reports Branch, Division of Biometry and Applied Sciences, NIMH, currently collects aggregate data on the percentage of the caseload age 65 or over in each service program of each mental health organization (see attachment). These data are collected as part of a biennial inventory of all mental health organizations designed to develop general purpose statistics on caseload, staffing, and financial characteristics. The Branch also conducts sample surveys of patients admitted to mental health organizations. These sample surveys are carried out approximately every 5 years and are designed to collect sociodemographic, clinical, and service data on the patients served in mental health organizations. The most recent survey of inpatient services was conducted in 1980-81. A sample patient survey of inpatient, outpatient, and partial care service programs of mental health organizations will be conducted in the spring of 1986. All data collected by the Branch are reported by mental health organizations on a voluntary basis.

1/ Study by the Staff of the U.S. General Accounting Office - "The Elderly Remain in Need of Mental Health Services" GAO/HRD-82-112, September 16, 1982.

The attachment shows the percentage of the caseload age 65 and over, by type of facility and type of service program, for the United States in 1983.

Overall, the highest percentages of the elderly are found in the caseloads of State and county mental hospitals and Veterans Administration medical centers. By type of service, the highest percentage occurs in the residential treatment services of State and county mental hospitals, where 53.1 percent of the caseload is age 65 or over. This is followed by the residential supportive services of Veterans Administration medical centers, with 38.2 percent; the inpatient services of State and county mental hospitals, with 24.1 percent; and the outpatient and inpatient services of Veterans Administration medical centers, with 16.0 percent and 15.7 percent, respectively.

The lowest percentages of the elderly in the caseload are found in the residential treatment services of private psychiatric hospitals and multiservice mental health organizations (this category includes Community Mental Health Centers) with 1.0 percent and 1.6 percent, respectively. These are followed by the residential supportive services of private psychiatric hospitals and the residential treatment services of Veterans Administration medical centers, with 2.8 percent and 3.2 percent, respectively. The elderly make up only 6.2 percent of the clientele in outpatient psychiatric clinics and in the outpatient services of community multiservice organizations. Generally, when the percentage of elderly in the caseload is less than 11.8 percent, the estimated percentage of those age 65 and over in the United States civilian population (Bureau of the Census, Current Population Reports: Population Estimates and Projections, Series P-25, No. 949), then the elderly are underrepresented within that service.

In addition to these ongoing data collection activities, there have been other recent special surveys of mental health services for the elderly. A 1984 NIMH-supported survey of Community Mental Health Centers (CMHCs) indicated that:

- The elderly represent about 6 percent of CMHC clientele.
- Slightly less than half of the CMHCs reporting provided specialized services designed for the elderly.
- Slightly less than 40 percent of CMHC professional staff have any specialty training in geriatrics.

Future Data Collection Requirements

In order to improve data collection on the mentally ill elderly who are in treatment, several modifications will be made in for current data collection procedures. These modifications are described below:

Aggregate Patient Data for General Hospitals. For the separate psychiatric services of non-Federal general hospitals, aggregate data will be provided on the percentage of the caseload that is age 65 or over for each type of service program. As non-Federal general hospitals assume increased importance in the delivery of mental health services, it becomes critical to develop this data base. Plans have already been finalized to include a question on age distribution of caseload in the 1986 combined Inventory of Mental Health Organizations and General Hospital Psychiatric Services.

Oversampling in the Sample Patient Surveys. To develop valid and reliable estimates of patient sociodemographic, clinical, and service characteristics for those in treatment who are age 65 and over, oversampling of this group will be required in future sample patient surveys. With current designs, it is possible to develop reliable estimates for age groups that constitute a large percentage of the service population, such as those between ages 18 and 64, but not for smaller patient populations, such as the elderly.

Sample Patient Cohorts. In order to understand the pathways into and out of treatment, cohorts of sample patients need to be followed over time. Little is currently known about these pathways for the elderly population. Hence, such research is a high priority for the future.

In addition to these modifications in ongoing data collection activities, beginning with Fiscal Year 1986 a new annual report will be required of each State mental health authority which will include data on services to the elderly in community mental health programs. In keeping with Section 1920(2) of the "Alcohol Abuse, Drug Abuse, and Mental Health Amendments of 1984," each State will be asked to report annually on the number and percentage of elderly being served in State-supported community mental health programs, the services available to the elderly, and the sources of funds for these services. This data is proposed to be a part of each State's annual block grant report.

Related Program Activities

A new contract has been let with the National Council of Community Mental Health Centers to develop and provide technical assistance to CMHC's in improving services to the elderly and other underserved groups.

Attachment

Table 1. Percentage of caseload age 65 and over, by type of facility and type of service program, United States, 1983

	Type of service program:				
	Inpatient	Residential treatment	Residential supportive	Partial care	Outpatient
Type of Organizations:					
State and county mental hospitals....	24.1	53.1	11.7	6.6	8.2
Private psychiatric hospitals...........	9.4	1.0	2.8	9.2	5.0
Veterans Administration medical centers 1/..........	15.7	3.2	38.2	11.5	16.0
Outpatient psychiatric clinics.......	NA 2/	NA	NA	NA	6.2
Partial care organizations.......	NA	NA	NA	6.7	NA
Multiservice mental health organizations...............	8.8	1.6	4.7	9.5	6.2
Community residential organizations..	NA	10.1	10.0	NA	NA

1/ Includes only the separate psychiatric services of these organizations.
2/ Denotes not applicable.

Report on the First Adjustment to the 1983 Determinations of Costs of Noncontributory Wage Credits for Military Service Before 1957

Consistent with the House Committee on Appropriations Report Number 99-289, the purpose of this report is to notify the Committee of the determination to transfer $3,220,000,000 from the general fund of the Treasury to the Old-Age and Survivors Insurance (OASI) and Disability Insurance (DI) trust funds on December 30, 1985.

The Social Security Amendments of 1983, Public Law 98-21, required that lump-sum transfers be made by May 20, 1983, from the general fund of the Treausry to the OASI and DI trust funds for costs attributable to noncontributory wage credits for military service performed between September 16, 1940, and December 31, 1956. Because the transfers included estimated future costs, provision was made for quinquennial determinations to adjust for actual experience and changes in assumptions affecting future costs. The first such determination is required in 1985. The law further requires that any resulting transfer of funds be accomplished within 30 days of the determination date. These requirements are contained in Section 217(g) of the Social Security Act. The FY 1985 Supplemental Appropriation, Public Law 99-88, includes an indefinite appropriation of "not to exceed" $3,500,000,000 to fund the cost of the mandatory payments to the Social Security trust funds.

Following these requirements, the Chief Actuary of the Social Security Administration has determined that $3,220,000,000 should be transferred from the general fund of the Treasury to the OASI and DI trust funds on December 30, 1985. This amount represents the estimated present value of all past and future costs attributable to pre-1957 military service wage credits, less the accumulated value of past reimbursements. The allocation of the transfer amount by trust fund is: $2,203,000,000 to the OASI trust fund, and $1,017,000,000 to the DI trust fund.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

National Institute of Arthritis, Diabetes, and
Digestive and Kidney Diseases

REPORT ON NIH-WIDE PLANS IN ENDOCRINE RESEARCH

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

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Digestive and Kidney Diseases

REPORT ON NIH-WIDE PLANS IN ENDOCRINE RESEARCH

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REPORT ON NIH-WIDE PLANS IN ENDOCRINE RESEARCH

Executive Summary

In House Report No. 99-289, the Committee on Appropriations requested that NIH prepare a report on NIH-wide plans with respect to endocrine research (p.50). The following is submitted in response to that request.

Although the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases has principal responsibility for conducting and supporting endocrine research, all NIH research institutes and divisions support aspects of research in endocrinology. The present report describes the recent advances that guide the direction of endocrine research and presents in detail NIH plans for further research in this field.

In 1978, a comprehensive evaluation of research needs in endocrinology was requested by the Senate Appropriations Committee, and in late 1979, that report was completed. The two-year study was conducted by a distinguished group of scientists and involved over 100 experts in the various facets of research in endocrinology and related metabolic diseases. The scientists described the state-of-the-art at that time and made a series of recommendations concerning research needs, directions, and opportunities.

In 1983, the NIH prepared a follow-up report to the Senate Committee on Appropriations concerning the progress, funding, organizational support and coordination of endocrine research during the period between 1979 and 1983. This report concluded that endocrinology represents one of the broadest areas of biomedical research endeavor falling within the missions of all the NIH institutes and the Division of Research Resources. It also concluded that significant progress had been achieved in this field between 1979 and 1983 and important advances had found application at the bedside.

The recommendations of the 1979 report have been, and continue to be, followed actively not only in terms of the support of extramural research and the conduct of intramural research in endocrinology, but also in terms of research training and the provision of specialized resources essential to this broad-based effort. A number of research advances since 1979 have been incorporated into clinical practice, while others have provided the foundation for new research directions of vast promise for the future. These advances provide unprecedented opportunities for studies which will characterize the clinical applicability of many of the new findings and which will generate new basic knowledge which may be expected to have major clinical application.

There is extensive cooperation among the different NIH institutes in the support and conduct of endocrine research. This includes multi-institute allocation of funds for joint support of research projects, joint issuance of program announcements and requests for grant applications, scientific collaboration between intramural scientists from different institutes, cooperative sponsorship of scientific conferences, and cooperative provision of material resources. The interdisciplinary nature of endocrinology underscores the need for such inter-institutional cooperation.

Because endocrine functions are basic to life itself, endocrine and endocrine-related disorders are among the most numerous and pervasive diseases of mankind. NIH's expanded support for research in this area reflects the importance that the NIH attaches to this research and represents a concrete expression of NIH's strong desire to develop further the base of knowledge in this field. NIH plans to continue its support for endocrine research in an effort to generate new knowledge in basic research with the potential for major clinical applications.

REPORT ON NIH-WIDE PLANS IN ENDOCRINE RESEARCH

1. INTRODUCTION

In its report on the fiscal year 1986 budget for the Department of Health and Human Services, the House Committee on Appropriations stated:

> "Endocrinology is currently an area of tremendous interest where scientific discoveries show great promise of providing new diagnostic technologies, therapies and cures for a host of human illness. The Committee was informed that in the past five years alone, over 50 hormones have been described that regulate cell growth, immune defense systems and nervous system function to name but a few. Unfortunately, only a small number of these new hormones have been purified and studied in detail. It is important that this work should be continued and expanded. The Institute is encouraged to work in cooperation with other NIH entities on endocrine research programs. The Committee requests a report no later than January 1986 on NIH-wide plans with respect to endocrine research." (House Report No. 99-289, page 50)

The following report has been prepared by the National Institutes of Health, of the Department of Health and Human Services, in response to this request.

2. NIH-WIDE PLANNED ACTIVITIES IN ENDOCRINE RESEARCH

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) supports basic and clinical research on the endocrine glands, their hormones and diseases associated with their dysfunction. The Institute maintains a strong basic and clinical research program in endocrinology utilizing innovative techniques in molecular biology, immunology, genetics and cell culture. In addition, a large proportion of the Institute's other research programs involve research in endocrinology. The majority of the Institute's resources are devoted to investigator-initiated research project grants through which investigators in the field pursue the most promising research opportunities in endocrinology. Consequently, the Institute's plans related to endocrine research emphasize the continued expansion of investigator-initiated studies oriented toward fundamental research in endocrinology. In addition, the Institute continues to stimulate and support multidisciplinary efforts to further elucidate endocrine processes and their regulation as well as clinical studies aimed at transferring advances in fundamental knowledge into clinical practice. Both clinical and basic efforts continue to be essential for the further development of improved strategies for the diagnosis, treatment, cure and ultimate prevention of endocrine disorders.

Extramural support across a broad range of research in endocrinology is provided primarily by the NIADDK Division of Diabetes, Endocrinology, and Metabolic Diseases. Within selected areas, extramural support of endocrine research is also provided by the Institute's Division of Arthritis, Musculoskeletal, and Skin Diseases, the Division of Digestive Diseases and Nutrition, and the Division of Kidney, Urologic and Hematologic Diseases. In addition, basic and clinical research in endocrinology is conducted by staff scientists in the Division of Intramural Research of the NIADDK.

Division of Diabetes, Endocrinology, and Metabolic Diseases

Endocrine diseases, including diabetes mellitus, diseases of the thyroid, parathyroid, adrenal, and pituitary glands, and growth disorders, are among the most common in medicine and have an enormous impact on both individual well-being and on the costs of medical care. Endocrine factors also play an important role in many diseases that are attributed primarily to other organ systems, including atherosclerosis, cardiovascular disorders, cancer, and psychiatric disorders. For these reasons, the Division's Endocrinology Research Program supports basic and clinical studies on the normal and abnormal functioning of the endocrine glands; the structure, function, and mechanism of action of the hormones produced; the effects of the hormones on various body functions; and the factors that relate to or modify the effects of the endocrine system.

To meet ongoing needs for advice on short- and long-term planning for research in endocrinology, the Division plans to recommend that an Endocrinology Research Program Advisory Committee be chartered by the Department. This committee will provide advice on research opportunities in endocrinology, areas in which research should be stimulated, research materials the Division should provide, conferences that should be convened or supported, and other program initiatives that would further progress in fundamental and clinical research in endocrinology.

A recent ad hoc Endocrinology Advisory Workgroup convened by the Division identified several areas of particular opportunity for research in endocrinology. This panel emphasized the importance of the endocrine aspects of cancer, cardiovascular disease, gastrointestinal disease, bone disease, aging, severe illness, stress, nutrition, obesity and fluid and electrolyte metabolism and urged the NIADDK to support interdisciplinary approaches to these problems. The panel recognized the potential of applications of new techniques in molecular and cell biology and immunology to advancement in understanding of endocrinology. Based on the panel's recommendations, the Division anticipates supporting expanded research in the hormonal regulation of gene expression, mapping of genes encoding hormones such as parathyroid hormone, the mechanism of hormone action, the structures of hormones and receptors, the transport of hormones to receptors, development of hormone analogues and antagonists, neuroendocrinology, the interaction between growth factors and releasing factors, endocrine transplantation and development of animal models, mutant cell lines and tissue culture methodologies relevant to endocrine disease.

The Division is also planning to explore the need for expanded support of both core resource facilities and pilot and feasibility projects through research center grant mechanisms. This would further stimulate the type of interdisciplinary approaches that were recommended by its Endocrinology Advisory Workgroup and that have been so successful in both its Diabetes and Endocrinology Research Centers and its Diabetes Research and Training Centers.

Additional research opportunities related more specifically to diabetes mellitus were identified at the recent Second National Conference on Diabetes which was convened under the auspices of the National Diabetes Advisory Board. Conference panels made recommendations to expand research related to the etiology of diabetes, the insulin gene, the secretion, biosynthesis and action of insulin, transplantation, and the various complications of diabetes. The Institute plans to pursue these opportunities as well, primarily through expanded support for investigator-initiated research project grants.

Molecular Endocrinology

The development of powerful recombinant DNA methods coupled with other recent advances in molecular biology have resulted in the unprecedented accumulation of knowledge about hormones. Prior to the application of these techniques, isolation of hormones involved laborious extraction and purification from large amounts of tissues. Advances in recombinant DNA techniques have already made possible the synthesis of potentially unlimited amounts of insulin, somatostatin and growth hormone. Currently, genes for a large number of other peptide hormones are being isolated and sequenced. Isolation of the genes encoding a hormone along with the regulatory portion of this gene also allows scientists to study the way in which production of the hormone is regulated. The NIADDK is supporting a significant number of projects designed to isolate and characterize genes encoding important hormones and to study the regulation of these genes.

An unexpected and very exciting benefit of recombinant DNA technology has been the ability to predict the existence of new hormones or neuropeptides which are currently unknown, based on the analysis of the cloned genes of known hormones. This novel approach resulted in the identification of a new and unsuspected neurohormone, called calcitonin gene related peptide (CGRP), from the gene structure encoding the known calcium regulating hormone, calcitonin. The "master gene" generates distinct mRNA's encoding either calcitonin or CGRP, depending upon the tissue in which the gene is expressed. Understanding the regulatory mechanisms that modulate tissue specific expression of genes to produce specific hormonal products has potential implications for understanding and treating a variety of disorders related to hormone deficiency or excess. Application of this approach to structural analyses of the gene to the many other peptide hormone genes which are currently being isolated could allow detection of other important and as yet unknown peptides. Identification of new peptide hormones and elucidation of their functions is a continuing and important part of the NIADDK's overall Endocrinology Research Program.

Utilizing new techniques of molecular biology, researchers also have made important advances in the characterization of hormone receptors. Recently, the gene for the human insulin receptor has been cloned. Elucidation of the insulin receptor structure will allow direct investigation of insulin action, and the role of the receptor in insulin resistant disease states such as type II diabetes or other hyperglycemic conditions. New knowledge of the interaction of insulin with its receptor has important implications for our knowledge of the interaction of other peptide hormones with their receptors. The Institute plans to stimulate additional studies to capitalize on research opportunities related to hormone-receptor interaction, mechanisms of hormone action, and hormone and receptor biosynthesis. In addition, expansion of research on the structure of receptor molecules, configuration of the receptor-hormone complex and effects of structural changes on the function and action of the hormones is anticipated.

Hormone Action

Thyroid disorders are among the most prevalent endocrine diseases and thyroid hormone is a major regulator of normal human development and metabolism. The NIADDK provides substantial support for research on normal and disordered thyroid function and the mechanism of action of thyroid hormone. Advances in our understanding of the mechanism of thyroid hormone action were the subject of a recent international conference organized by NIADDK. Significant progress has been made in identifying subcellular sites of thyroid hormone action, the receptors for thyroid hormones, and the mechanisms by which thyroid hormone controls metabolic processes. New knowledge is also developing about disease states due to resistance to thyroid hormone. With NIADDK support, investigators are expanding research efforts aimed at further characterization of receptors for thyroid hormone, the role of thyroid hormone in regulating gene expression and other cellular processes, and the treatment of patients with resistance to thyroid hormone.

Another area of particular research emphasis involves the mechanism of action of counterregulatory hormones that influence or oppose the action of other hormones, especially in relation to glucose homeostasis and the development of diabetes mellitus. Maintaining normal blood sugar levels involves several hormones, including insulin, glucagon, and epinephrine. Significant progress is being made in unraveling the complex interactions among the various hormones regulating glucose metabolism, and further studies are planned. The Institute anticipates an expansion of investigator-initiated studies in these and other important areas of outstanding scientific opportunity related to the mechanism of hormone action.

Autoimmunity and Environmental Factors

The NIADDK plans to intensify research on autoimmunity related to endocrine diseases, particularly as it is involved in insulin dependent diabetes mellitus (IDDM), thyroid disease, hypoparathyroidism, and hypoadrenalism. In autoimmunity, the constituents of the immune system turn against (or attack) the body's own tissues, often causing disease. Some forms of IDDM and autoimmune thyroid disease are characterized by the autoimmune destruction of the tissues involved. The role of the immune system and its components in this process, predisposing immune factors, as well as the source of the initial sensitizing antigen, need to be further defined. Further work is also needed to develop indices in patients with autoimmune hyperthyroidism to predict resolution after medical treatment or requirement for surgery or radiotherapy.

The role of environmental factors in endocrine disease is a new and potentially exciting research area. Several clinical endocrine disorders have been reported after hormonal contamination of food. Significant questions about the direct and indirect effects of chemicals, mycotoxins and other environmental pollutants on endocrine and neuroendocrine systems are being recognized. The NIADDK plans to provide expanded support in this important area of emerging research interest.

Endocrine Transplantation

Significant advances have occurred in the past few years in transplantation of endocrine tissues, especially involving transplantation of pancreatic islet cells, which are responsible for the secretion of insulin. It is now possible to prevent rejection of isolated animal islets transplanted between different strains of mice as well as between different species (rat to mouse). Methods for separation of islet cells from whole pancreas have been improved, so that increased yields of useful cells are obtained without contamination by acinar tissue which contains destructive digestive enzymes. Studies in animals have suggested that islet cell grafts in diabetic animals can arrest, reverse and, in some cases, prevent complications of diabetes. These and other advances have brought islet transplantation to the threshold of being applied to human diabetic patients. However, the timely and effective application of these results to human studies depends on the assurance that islet transplantation can be done in a safe, reliable and reproducible manner. Also, various problems associated with islet procurement, preservation, and immune rejection need to be addressed in humans.

In October 1984, a workshop was held which brought together many of the expert investigators in the field of islet transplantation, to discuss the future of islet transplants and transplants of other endocrine organs. Their considerations included an assessment of past transplantation efforts, areas in which further research is needed, and recommendations for future activities. In response to these recommendations, the Institute is considering the development of new programs which may include some centralized research resources, a registry to follow patient outcomes and strategies, multicenter research efforts, and training opportunities to expand the cadre of investigators proficient in the area of endocrine cell transplantation. It is anticipated that the technology and knowledge acquired with respect to islet transplantation will contribute to transplantation efforts of other endocrine cells or organs.

Neuroendocrinology

Neuropeptides that had long been predicted to exist because of their observed effects, like growth hormone releasing factor (GRF) and corticotropin releasing factor (CRF), only have been isolated and sequenced recently. The availability of these materials have allowed researchers to uncover new ways to treat some endocrine disorders. For example, recently it has been shown that in many patients, growth hormone deficiency is due to a primary deficiency of hypothalamic GRF, rather than growth hormone (GH) itself. GRF, therefore, may be a substitute treatment in some children with hypopituitary short stature. Additionally, the recent observation that GH release can be achieved with intranasal administration of GRF offers hope that this mode of delivery, rather than injections, may be feasible in the future. The NIADDK anticipates expanded support of clinical studies involving GRF and the development of analogues of GRF with useful properties. For example, a GRF antagonist might be useful in the therapy of acromegaly in which excessive growth hormone is produced.

Studies with CRF have shown it to be a major integrator of the neural and endocrine responses to stress. Ongoing studies with this peptide hormone will advance our understanding of the pathogenesis of Cushing's disease, a form of hypercortisolism. NIADDK-supported investigators are developing new analogues of CRF which may be useful in therapy of hyper- or hypocortisolism. Analogues of hormones with altered functions, targets or metabolism could be very useful in the treatment of many other known disorders of endocrine origin. Synthesis of hormone analogues and research on their basic and clinical applications are goals of a number of projects supported by the NIADDK.

Other neuropeptides whose existence is predicted are still being sought. NIADDK-supported researchers are working to identify and purify neuropeptides which inhibit prolactin secretion from the pituitary. Such a factor, if available, could be important in suppressing metastatic breast cancer of the prolactin dependent type.

Endocrine Regulation of Bone Metabolism

Hormones, including the calciferols, parathyroid hormone, calcitonin, and estrogens, are major regulators of bone formation, remodeling, structure, and function. Conditions of hormone excess or deficiency frequently are manifested through effects on the skeletal system. Hormones and their analogues are often used as therapeutic agents in skeletal diseases. There are many unresolved issues of clinical relevance concerning the effects of hormones on the skeletal system that can best be answered using *in vitro* systems in which variables can be controlled. In vitro studies are particularly needed to define whether skeletal effects of hormones occur as a result of the direct action of the hormone in bone or whether they are mediated through other factors stimulated by the hormone.

The Institute plans to initiate studies to define the direct effects of hormones or analogues that regulate bone metabolism in appropriate in vitro systems. The long-term effects of hormones on bone cells can be studied in tissue culture, and parameters such as calcium accumulation, cell growth, and cell differentiation can be evaluated. With advances in the development of growth systems for bone cells, studies of several months duration could be carried out. The development of agents that build or modify or destroy bone can be tested in these systems as well. Such modifying agents could have tremendous therapeutic potential in a number of conditions.

National Hormone and Pituitary Program

The National Hormone and Pituitary Program (NHPP) is an important research resource supported by the Institute since 1963. The NHPP distributes over 100 types of research materials, many of which are not available from any other source. Through the NHPP, human cadaver pituitaries are collected for extraction and purification of pituitary-derived hormones and production of their antisera. Approximately 5,000 individual awards of materials are made to investigators annually for use in research or clinical protocols. Surveys of the leading endocrinology journals show that materials provided by the NHPP were used in more than half of the published studies. Until recently, 2,300 children with growth hormone deficiency were receiving therapy with NHPP-supplied human growth hormone (hGH) under approved research protocols. Recently, however, three patients who had received early preparations of hGH died from Creutzfeldt-Jakob Disease (CJD). Consequently, the NHPP ceased distribution of hGH because it was thought that some preparations of pituitary-derived hGH may have been contaminated with the agent responsible for CJD.

With regard to the issue of CJD, the feasibility of demonstrating exclusion of the infectious agent of CJD during hormone purification is being examined. Studies to determine the infectivity of preparations previously distributed and the incidence of CJD among growth hormone recipients are underway. Also in progress is an epidemiologic follow-up of hGH recipients to ascertain the current health status of all recipients of pituitary hormones supplied by the NHPP. The Institute plans to continue to emphasize this important area of public concern and scientific opportunity.

Distribution of materials for nonhuman use by the NHPP has not been affected by the CJD issue. In fact, after hearing concerns about this expressed by scientists at the June 1985 Endocrine Society meeting, an announcement of the continued availability of all NHPP materials for nonhuman use was published in the leading endocrinology journals.

The NIADDK convened a panel of leading endocrinologists to provide advice on how the NHPP might best meet research needs and respond to new research opportunities in endocrinology. This committee emphasized the great importance of this research resource to the advancement of our understanding of endocrinology. It recommended that the NIADDK continue to support distribution of both human and animal pituitary hormones and their antisera for laboratory research. This NHPP advisory committee also made several major recommendations for expansion of the program.

First, the Institute now plans to distribute intact pituitaries to investigators, as well as extracting and purifying pituitary hormones. In the past, distribution of the organs had been limited because of the need to maximize the production of growth hormone for clinical studies in growth hormone deficient children. However, with the cessation of distribution of pituitary growth hormone for clinical purposes and the availability of growth hormone from recombinant sources, the need for production of pituitary-derived human growth hormone has diminished. The Institute anticipates that distribution of intact pituitaries will provide opportunities for new avenues of research to be pursued. In addition, pituitary-derived hormones will continue to be purified and distributed for non-clinical research purposes. Since the pituitary appears to produce each of its hormones in multiple forms, research with a single recombinant form of hormone, even if available, may not provide the same information as the pituitary-derived hormone itself. Another recommendation from this panel was that the NHPP expand the program to include the distribution of new products such as neuropeptides, other non-pituitary hormones or regulatory factors for which there are no readily available sources of characterized materials, and antisera with peptide sequence specificity data. Also, the feasibility of establishing a bank of molecular probes for hormones or neuropeptides will be explored.

Division of Arthritis, Musculoskeletal and Skin Diseases

Sex Hormones and Osteoporosis

Osteoporosis affects as many as 15 to 20 million Americans, primarily postmenopausal women, causing hip fractures, spinal crush fractures, and wrist fractures. The condition affects over half of women above 45 years of age and 90 percent of women above age 75. Each year, 1.3 million fractures are attributable to osteoporosis.

Normal bone metabolism consists of a complex balance between continual resorption and formation of bone. In osteoporosis, the control is out of balance, and less dense, weaker bone is produced. While many factors have been related to the development of osteoporosis, a deficiency of estrogen in postmenopausal or oophorectomized women is clearly related to an accelerated loss of bone mineral mass.

Estrogen supplementation in postmenopausal women has been determined in clinical studies to be effective in prevention of osteoporosis. Side effects, including increased risk of endometrial cancer and a return of vaginal bleeding, have reduced the general acceptance of this drug. Lower doses of estrogen may reduce the negative aspects and retain the protective aspects. Progestins may eliminate this increased risk of endometrial cancer but may induce other problems such as generating an unfavorable blood lipid profile. There is great need to evaluate risks and benefits of various combinations and doses of these hormones, delivery schedules, and delivery routes.

In April 1984, the NIADDK and the Office of Medical Applications of Research supported a Consensus Development Conference on Osteoporosis. Participants in this meeting described the current state of knowledge on causes and prevention of osteoporosis. One of the recommendations of the Conference Panel was to support "studies to determine the optimal regimen of gonadal hormones (estrogens and/or progestins) for prevention of bone loss and fracture."

The Institute also plans to fund more studies on alterations in basic bone metabolism associated with osteoporosis. Such studies would elucidate further the mechanisms of bone growth and remodeling and their regulation through local and systemic coupling factors. Particular attention will be made to rapid endocrine changes occurring at menopause. Identification of mediating factors will better explain the underlying processes of osteoporosis and provide the basis for future therapies.

Another area of increased emphasis will be research on local factors which control the deposition of bone and its constant metabolic flux. The two major cell types involved in this process are osteoblasts, which form new bone, and osteoclasts, which resorb old bone. Many factors have been shown to directly influence bone metabolism. A peptide derived from macrophages has been shown to stimulate the growth of bone cells. In previous studies, lymphocytes had been shown to participate in control of the lymphocytes had been shown to participate in control of the resorption phase of bone remodeling. Now the immune system appears to play a role in providing both up-regulation (bone growth) and down-regulation (bone resorption) of bone metabolism. Other factors have been derived from platelets and even bone itself. One study has demonstrated a factor derived from osteoclasts that may stimulate osteoblasts and thus serve as a coupling factor.

The basis for the recent advances and the promise for future discoveries lies primarily in improved culture systems. Pure cell lines are becoming available in many laboratories. Through the use of cell free growth media and special harvesting procedures, the cell lineage starts pure and does not differentiate even after many replication cycles. New markers, such as osteoclast cell surface monoclonal antibodies, facilitate positive identification of cell type.

Endocrine Abnormalities in Arthritis

Arthritic conditions are frequently associated with endocrine abnormalities and the Institute will continue to support research in this area. One topic being investigated is the abnormal level of androgens and estrogens in patients with systemic lupus erythematosus (SLE). Females with active disease have recently been found to have low adrenal androgen levels. Earlier reports described a defect in the metabolism of estradiol in women with SLE. Further investigations involving the administration of 19-nor-testosterone to human females in an attempt to reverse the disease process will be coupled with studies of strains of SLE mice treated with a variety of androgens, such as etiocholanolone and dehydroepiandrosterone, and estrogens like 16-hydroxytestosterone and estriol to examine the role these agents play in the morbidity and mortality of SLE in these strains.

Systemic sclerosis (scleroderma) is another condition in which a hormone, serotonin, has an apparent mediating effect. The use of ketanserin, a selective antagonist of serotonin, in patients with Raynaud's phenomenon, an early manifestation of scleroderma, was of benefit to 80 percent of participants in a pilot study of 30 patients. This finding will be followed up by additional studies.

Cutaneous Expression of Hormonal Changes

The Skin Diseases program is supporting studies on the effects of hormones on skin and skin appendages, with major interest on sebaceous glands and hair follicles related to the problems of acne and alopecia. The growth and metabolism of human sebaceous glands are affected greatly by hormones, particularly in adolescence and pregnancy. Hair follicle growth is another visible manifestation of systemic changes in hormone level.

Division of Digestive Diseases and Nutrition

In recent years the gastrointestinal tract has been recognized as an endocrine-responsive organ and the site of production of numerous hormones. A variety of functions of the gastrointestinal tract, the pancreas and the gallbladder is closely regulated by a number of hormones. Many peptides are now recognized as "gut" hormones, produced in or acting on the gastrointestinal tract. Hormone-producing cells in the gastrointestinal tract are sparsely distributed in cells lining the stomach, the small and large bowel, and the pancreas. The hormones secreted by some of these cells directly affect the function of adjacent cells, a relationship called "paracrine," in distinction to the classic endocrine cells which secrete hormones transported by blood to target cells at more distant sites.

Although endocrine and paracrine functions are usually thought to be independent, recent evidence suggests that the pancreatic islets, responsible for hormone production, communicate and influence the acinar cells which are responsible for production of digestive enzymes. Studies have revealed physical contact between these tissues, and demonstrated communication at the molecular level. Insulin, which primarily regulates blood glucose levels, has been shown to directly influence mRNA production for a major digestive enzyme, amylase, as well as to enhance the effect of other hormones responsible for inducing the secretion of pancreatic digestive juices. Glucagon is also known to control pancreatic exocrine cell function.

The need and opportunity now exist to focus attention on the interactions of the exocrine and endocrine pancreas under both physiological and pathological conditions. The exocrine consequences of endocrine disorders like diabetes and the endocrine consequences of exocrine diseases like cystic fibrosis are major issues in current treatment modalities for these diseases. The influence of endocrine and neuroendocrine stimuli on exocrine function has important physiological consequences for secretion in the gastrointestinal system.

Diarrhea is a major health problem and is life-threatening when it leads to dehydration and electrolyte imbalance. Diarrhea may be caused by infectious agents, or by noninfectious agents such as alteration of neurohormonal control of gut function or gut hormone-producing tumors. Ideally, treatment should be directed at a specific cause; unfortunately, in noninfectious diarrhea it is not always possible to identify the cause of diarrhea, and so symptomatic treatment may be indicated.

Somatostatin is an endocrine hormone secreted by the pancreas and neural tissue throughout the gastrointestinal tract. It stimulates absorption of ions, inhibits water and electrolyte secretion and regulates the release of a number of gastrointestinal hormones including insulin and glucagon. In recent studies somatostatin analogues demonstrated promising results in selectively inhibiting intestinal ion transport in animals. It may be possible, therefore, to develop analogues of somatostatin with specific intestinal actions useful in the treatment of diarrhea.

Division of Kidney, Urologic, and Hematologic Diseases

The endocrine and metabolic consequences of chronic renal disease and uremia are numerous since the kidney has, in addition to its excretory functions, an important role in the biosynthesis or metabolism of various hormones. For example, erythropoietin, a hormone-like substance secreted by the kidney, stimulates the production of blood cells by the bone marrow. Nearly all of the 70,000 patients in the U.S. with chronic renal failure develop anemia due to impaired erythropoietin synthesis. Recently, investigators succeeded in cloning the gene for erythropoietin, and extremely rapid advances in knowledge of this factor have occurred. Areas of investigation include the mechanism of production of erythropoietin in the kidney, its interaction with renal prostaglandins, and its effects at both renal and bone marrow sites in chronic renal failure. Large scale production of erythropoietin obtained through DNA cloning offers the possibility of treatment of the anemia of renal failure. Future research efforts will be focused on methods for large scale production and on the fundamental and clinical effects of erythropoietin. In addition, work on other erythroid factors that regulate blood formation and differentiation is also a priority of the Institute.

Another hormone produced by the kidney is the potent vitamin D metabolite, $1,25\text{-}(OH)_2D_3$. Crippling bone disease and severe growth failure sometimes occur in children with renal insufficiency. A multicenter clinical trial to assess the safety and efficacy of early therapeutic intervention with $1,25\text{-}(OH)_2D_3$ in children with renal failure is underway. This trial is aimed at preventing growth failure and/or promoting growth in this patient population. Also, investigation is needed of other nutritional factors, such as vitamin A, aluminum, manganese, and silicon, as they relate to vitamin D action and to bone structure and maintenance.

In addition to its important role in the bone resorption process and hence the modeling and remodeling of bone, $1,25\text{-}(OH)_2D_3$ acts directly on the intestine to promote calcium absorption. Calcium absorption in turn determines calcium excretion. Thus, vitamin D metabolites are a major factor in hypercalciuric states (high calcium levels in the urine) which are in turn associated with calcium nephrolithiasis (calcium stones in the kidney).

Elucidation of the entire pathway of vitamin D metabolism is needed for understanding which forms of the vitamin are metabolically active and what the regulators of the vitamin are. Improved assays of the vitamin D metabolites are needed to define their roles both in normal physiology and in clinical disorders.

The kidney is the site of action of hormones that regulate fluid and electrolyte excretion and therefore body content of water and salt. Such a hormone is antidiuretic hormone (ADH). It is being extensively investigated in terms of its synthesis, its effect on the various segments of the nephron, and its modulation and/or interaction with other hormones or hormone-like substances including the prostaglandins, renin, mineralocorticoids, angiotensin, glucocorticoids, vitamin D, parathyroid hormone, catecholamines (epinephrine, norepinephrine), acetylcholine, dopamine and insulin. The hormone aldosterone is a principal regulator of potassium excretion by the kidney. Studies in progress not only redefine the role of aldosterone but suggest that other hormones including ADH may also contribute to maintenance of potassium homeostasis by the kidney under a variety of physiological conditions. Suppression of ADH levels by water ingestion may itself regulate the potassium secretory apparatus. However, further research is needed to clarify the roles of the hormones responsible for maintaining potassium balance.

The newly discovered vasoactive polypeptide--Atrial Natriuretic Factor (ANF)--has natriuretic, diuretic, and smooth muscle relaxant effects. Although the site and mechanism of action of ANF in the kidney are not known, its function is not limited to relaxation of vascular tissue since the response in the kidney cannot be mimicked by the known vasodilators. ANF seems to have a unique combination of functional properties which include increasing glomerular filtration rate and urinary sodium excretion without a sustained increase in renal blood flow, and decreasing blood pressure, plasma renin activity, and aldosterone. Active investigation of the physiological and potential therapeutic properties of this hormone is planned.

Benign prostatic hyperplasia (BPH) is a non-cancerous condition characterized by excessive growth of the prostate gland such that urination may be impaired (obstructive uropathy). Typically, the overgrowth of the prostate gland begins in the fourth or fifth decade and progresses to cause obstruction in the 6th decade of life. Certain hormones (androgens and estrogens) may act in a permissive manner, enabling the prostate to renew its growth in the aging male. An effort is being made to develop prostatic cell lines for use in studying the mechanism of action of androgen and facilitating studies on isolation, characterization and purification of the prostatic androgen receptor. Ultimately, it should be possible to clone the androgen receptor gene or genes and deduce its sequence and structural specificity. Although androgens have a pervasive role in prostate growth, it is now thought that other primary factors such as prostate growth factor may act in concert with androgens to stimulate prostatic growth in the adult man. Further work is needed to define the role of these factors in causing BPH.

Division of Intramural Research

The Institute's intramural research programs encompass broad-based endocrine research efforts that involve both clinical and basic studies related in part to the mechanism of action of the following hormones and their receptors.

Insulin and Other Polypeptide Hormones

One of the central problems in understanding important diseases such as diabetes mellitus is the need for a more complete understanding of the mechanism of action of insulin. Recently, the detailed scheme of the biosynthesis of the insulin receptor has been formulated. The receptor is synthesized by way of a high molecular weight precursor which is then processed and cleaved into two subunits that are inserted into the plasma membrane of many cells. This information offers a tremendous opportunity to study the nature of the receptor in a number of disease-related states such as non-insulin dependent diabetes. We know that a number of biochemical steps are involved, and there is preliminary evidence to suggest that there may be defects in several of these events in clinical diseases. Thus, studies in mutant cells in which these precise defects can be found will be extremely useful. This will enable scientists to further determine both the normal and the abnormal processing of this important cell surface constituent. Further, it is known that this component of the cell, that is, the insulin receptor, is highly regulated. Studies up until the present have demonstrated that the receptor is taken up by the cell by a process known as receptor-mediated endocytosis. A better understanding of this process is essential to understanding the nature and details of receptor regulation. This is not only true for insulin but is true for a variety of other polypeptide hormones. Thus, the events involved in the endocytosis and recycling of the receptor now can be addressed in much greater detail.

One of the most dramatic findings of recent research has been the cloning of the gene for the insulin receptor. This was made possible from data based on information from the insulin proreceptor which gave an idea of the structure of the receptor. The cloning, however, has provided a detailed structure of each of the components of the receptor. It is known that the receptor consists of a binding portion and another portion that spans the membrane of the cell. This portion of the receptor is an enzyme which can act upon itself, and it is likely that this important event is involved in the transduction of the insulin effect across the cell membrane. The cloning data and the detailed structure make it possible now at the DNA level to construct both normal and abnormal insulin receptors and to add or delete specific portions of the receptor so that their function may be individually studied. These mutant genes can then be inserted into other cells, and the function of these mutations can then be ascertained. Further, it is possible to generate antibodies to the various portions of this molecule to further elucidate the functions of the different regions of the molecule. Finally, it is important to emphasize that these studies related to the insulin receptor provide a model that can be applied to other polypeptide hormone receptors as well.

Glycoprotein Hormones and Hypothalamic Releasing Factors

Considerable information has accumulated about the nature of the glycoprotein hormones, that is, TSH, FSH, LH made by the pituitary and hCG made by placenta. These hormones are very important in regulating thyroid hormone secretion and the regulation of gonadal function. Further, it is known that hypothalamic factors stimulate the release of hormones from the pituitary. Recent studies have indicated that the processing of the glycoprotein hormones is extremely important in determining their biologic effect and further, that the stimulatory hypothalamic hormones may play an important role in either the processing of these hormones or the signaling of their release through a different intracellular mechanism. Some examples of specific studies in progress include the effects of thyrotropin releasing hormone (TRH) on the synthesis, processing, regulation and action of thyroid stimulating hormone (TSH); analysis of TSH carbohydrate structure in various physiologic states; molecular basis of thyroid hormone resistance; and regulation of TSH biologic activity by thyroid hormone and TRH. In addition, the molecular mechanisms underlying the neuroendocrine occurrence, biosynthesis, and function of neuroendocrine peptides and proteins are being studied, with emphasis on the neuropeptide hormones oxytocin and vasopressin. The importance of these studies is clear for our understanding of highly relevant problems such as thyroid function, fertility, and other related problems.

Parathyroid Hormone

Another area of considerable interest involves the function of parathyroid hormone, a hormone that is very important in the regulation of calcium metabolism. Recent findings have suggested that there may be some form of growth factor that is important in regulating parathyroid growth. This may be of critical importance in certain parathyroid states and tumors of the parathyroid gland. Further, it is also possible that these growth factors may have an important regulatory role related to parathyroid hormone secretion. Analogous to other polypeptide hormones, for example glucagon and ACTP, parathyroid hormone interacts with specific receptors at the cell surface. A coupling protein, which in turn is activated by guanine nucleotides, links parathyroid hormone receptor to adenylate cyclase, the enzyme causing formation of cyclic AMP, the messenger that causes hormone stimulation of cell processes. Great progress has been made in understanding the nature of this coupling function. It is known, for instance, that a protein involved binds certain kinds of simple molecules and that these molecules are very important in permitting this coupling function to take place. It has also been demonstrated that there are disease states in which this process is defective and that in these diseases there is defective biologic response to parathyroid hormone. Future studies will apply this new information to clone the genes for a portion of this coupling subunit and to more fully define the relationship of this coupling unit to the transduction effect.

Metabolic Regulation and Vitamin D

Endocrine studies of metabolism are investigating the mechanism of action of hormones controlling ion transport, mineral metabolism, and the immunological and pathological factors mediating kidney disorders. Systems under study include renal and skeletal tissue, transgenic mice, isolated cells (kidney and parathyroid) in culture, and hormone receptors for adrenergic receptors, parathyroid hormone and vitamin D metabolites. An extremely important finding in recent years related to bone metabolism is the discovery that vitamin D, a nutrient vitamin, acts essentially like a hormone. This material binds to specific nuclear receptors and is extremely important in regulating gastrointestinal calcium transport in the calcification of bone. Studies related to vitamin D have important implications for such diseases as osteoporosis. Recent studies have exploited mutant cells from patients who have resistance to vitamin D. These mutant cells will provide new important information on the mechanism of action of this important nutrient hormone. Thus, it will be possible to define the various levels at which vitamin D acts within an individual cell, that is, at the level of the cell membrane, at the level of a possible cytoplasmic binding protein and, more specifically, at the level of the transcriptional unit within the nucleus of the cell.

Growth Hormone

Growth hormone is an important hormone related to somatic growth. When present in excess, it causes diseases such as acromegaly and gigantism. New analogues of biologically active hormones, such as somatostatin, have recently been synthesized, and preliminary studies indicate that these analogues may be very important in suppressing growth hormone release in disease states such as acromegaly. Clinical trials are under way at present and will be continued when new analogues become available in the future. These analogues have also proven to be extremely important in controlling secretion of other gastrointestinal hormones such as gastrin, glucagon, and insulin. Thus, they have important implications for both the management of gastrointestinal and pituitary function.

Thyroid Hormone

It has recently become clear that thyroid hormone is an important regulator of the genes that control a number of enzymes related to intermediary metabolism. Thus, these enzymes relate to the processes by which glucose, fats and proteins are metabolized. The cloning of the genes for several of these enzymes now makes it possible to more specifically understand how a hormone such as thyroid hormone is involved in these processes; an extremely important application in endocrinology over the next several years will be to further elucidate more specific mechanisms by which these processes are regulated. With respect to clinical endocrinology, various studies now in progress are focused on thyroid biochemistry and pathophysiology. These include studies of the interaction of thyroxine and triiodothyronine with the circulating plasma proteins that bind these hormones; thyroid hormone metabolism and the role of physiological regulation in transport of thyroid hormone into cells; thyroid hormone action on the cell nucleus and the regulation of protein synthesis; and studies related specifically to thyroid disease.

Connective Tissue Diseases

The intramural program is also studying hormonal involvement in the pathogenesis and treatment of connective tissue diseases. Systemic lupus erythematosus (SLE) is the focus of many of these studies because of the clear effect of sex hormones. SLE is primarily a disease of women, and many of the women with SLE exhibit abnormal hormonal levels.

Therapeutic studies are currently focused on SLE patients with nephritis. Patients with a mild degree of nephritic scarring respond to treatment with low doses of corticosteroids combined with oral azathioprine or oral cyclophosphamide. Long-term follow-up of patients demonstrates that this addition of immunosuppressive cytotoxic drugs is a considerable enhancement over conventional corticosteroid therapy.

Investigations on the pathogenesis of SLE are being pursued using inbred New Zealand mice that exhibit syndromes closely resembling the disease in humans. The disease in mice is caused by autoimmunity. The severity of its expression can be modified by environmental as well as hormonal factors. Recent studies have shown that communications between cells by cytokines is an important factor in the expression of immune abnormalities. The cytokines, low molecular weight mediators, produced by autoimmune mice are different from normal mice. Further, the autoimmune defects can be produced in normal mice by manipulation of these cell-to-cell mediators.

A related basic study is defining the receptor on mast cells which leads to the release of mediators of allergic and inflammatory reactions. Improved procedures for isolating the receptor are being developed, thus enhancing the ability to perform structural and genetic studies. This research may lead to a greater understanding of the mechanism of action involved and may also allow for the development of therapeutic manipulations of the immune system.

The Institute plans to continue and expand these studies on the hormonal and local factor influences on the expression of autoimmunity and inflammation.

NATIONAL CANCER INSTITUTE

Extramural Research

The National Cancer Institute (NCI) has had a long-term commitment to research on the classical steroid hormones such as the estrogens and the androgens, because they frequently act as carcinogens in sensitive target organs of the breast and the uro-genital tract, and because growth of tumors of this type is often dependent on these hormones. Considerable effort is being placed on further defining the roles of estrogen, progesterone and androgen receptors in classifying these tumors and in helping to select appropriate anti-steroid hormones as therapeutic agents for these diseases. The loss of hormone-dependence of carcinomas of this type is consistent with the most aggressive tumors and has tremendous prognostic importance. New evidence suggests that the steroid responses of both breast and prostate epithelial cells may be mediated by interaction with adjacent normal stromal cells, perhaps through a growth factor produced in the stroma, which further complicates the clinical picture. Other applications of the study of receptor biology include the development of a blood test for the diagnosis of carcinoma of the uterus, based on hormone sensitivity.

In sharp contrast to effects of the sex steroids, the corticosteroid hormones have antiproliferative effects on solid tumor cell populations as well as abnormal lymphocytes, and thus have important application to chemotherapy in cancer patients. Research into the complex mechanism whereby glucocorticoids bind up specific molecules within target cells and subsequently cause new cellular proteins to be made and sometimes cause cells to lyse, is proceeding at an ever accelerated rate. It is now clear that the steroid-binding-molecules move quickly to specific parts of the cell's DNA, become physically attached to certain genes and activate those genes. The resulting new proteins may then become either positive or negative effectors within the cell. Important basic research on the mechanism of action of this hormone is also establishing an information base that should accelerate similar projects with the other steroids.

Another important area of endocrine research being emphasized throughout this Institute emphasizes protein factors that may act as either autocrine, paracrine or endocrine growth factors. Some of these were described years ago as factors for normal endothelial and epidermal cell growth and only recently have been shown to relate directly to cancer because of their association with products of oncogenes. Evidence of the homology of platelet-derived-growth factor to the *sis* oncogene protein was one of the first demonstrations. A short time later, scientists provided evidence that the product of the *erb*-B oncogene was actually a truncated cell surface receptor for epidermal growth factor.

Research on these "normal" growth factors and their normal cell receptors is now seen as very significant to the diagnosis, treatment and prognosis of cancer. The epidermal growth factor receptor, especially, is seen as an important tool in more applied research. Levels of this receptor in head and neck tumors seem to correlate with the tumors' clinical behavior. The number of epidermal growth factor receptors in certain carcinomas of the pancreas is abnormally high, and evidence suggests that there may be some correlation to specific changes in the tumor cell chromosomes. The presence of truncated receptors in tumors holds out the possibility that monoclonal antibodies might be produced for use as therapeutic agents against these abnormal proteins, while the normal cells would be unaffected by this treatment.

As individual tumor cell types have been analyzed more carefully, the presence of unique growth factors produced by individual tumors has become very apparent. The purification of certain of these "Tumor Growth Factors" and the synthetic production of one of them has allowed the pursuit of very sophisticated experiments and has provided detailed information about their mode of action at the cell level and in whole animals. The excessive production of growth factors by specific tumors has also spurred applied research projects into development of diagnostic screening tests on blood and urine that might detect cancer before it is clinically apparent. The therapeutic usefulness of many categories of biologic response modifiers produced by normal cells and tissues as well as tumors, or of antibodies against them, has been the subject of several recent program announcements from this Institute.

Other factors produced by tissues that are not usually classified as endocrine also have important effects on tumors. One, produced by blood cells, is called Tumor Necrosis Factor. This factor is cytotoxic for a number of human tumor cell lines and is also effective in destroying certain tumors in animals; however, it has no effect on normal cells. Therapeutic applications should soon be possible using this human factor because DNA recombinant biology has permitted the isolation and purification of this previously rare factor in large quantities.

Purification of another rare human growth factor from blood cells has now been completed that stimulates the production of granulocytes and macrophages from precursor bone marrow cells. Sufficient quantities of this granulocyte-macrophage-colony-stimulating-factor, produced by recombinant genetic techniques, is now available for research on the molecular action of this factor. Further use of these important growth factors in the therapy of cancer patients also has considerable potential. Synchronized use of factors of this type might protect the normal bone marrow stem cells from the toxic effects of chemotherapy and might later be used to stimulate healthy levels of white blood cells after the chemotherapy. Certainly the availability of these highly purified protein factors sets the stage for a new era in cancer treatment.

Intramural Research

Certain areas of oncogene research also relate to the effects of steroids on mammary cancer. Recent evidence with a human breast tumor cell line indicates that the presence in the cells of an active oncogene called H-ras completely eliminates the usual estrogen requirement of these cells for growth. Further research on the ability of this oncogene to short circuit the response process is proceeding in a number of laboratories.

Insulin-like growth factors--IGF-I and IGF-II in rats--are structurally related to insulin and are growth factors for a variety of cells in culture. Receptors for these IGFs have been identified, isolated, and partially characterized. Attempts are under way to develop monoclonal antibodies to the rat type II IGF receptor. The availability of monoclonal antibodies to this receptor will make it possible to study the local production and mechanism of action of this IGF in vitro, which should reflect the normal growth process. Information gained from these studies may have implications for the growth control of tumor cells in vivo.

Understanding the basic mechanisms involved in hormone-receptor interactions which result in controlled or uncontrolled growth is likely to be of great value in understanding the mechanisms leading to the formation of cancer cells. The recent identification of a plasma membrane receptor for thyroid hormone has enabled the study of the molecular mechanism of transport of this hormone into animal cells and the subsequent translocation from the cytoplasm to the nucleus where biologic actions occur.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Extramural Program

The National Heart, Lung, and Blood Institute (NHLBI) provides leadership for a national research program in diseases of the heart, blood vessels, lungs, and blood, and in the use of blood and the management of blood resources. The Institute supports endocrinologic research in all programmatic areas.

Endocrinologic studies have contributed greatly to the understanding of blood pressure regulation. The major systems believed to underlie blood pressure control are in part dependent on the actions of hormones and other vasoactive substances. For example, peptides that are secreted by the heart's atrium result in the excretion of sodium and water, relaxation of smooth muscle in blood vessels, and a decrease in renin secretion. Current studies are focusing on the role that these atrial natriuretic peptides play in regulating the sodium balance, blood volume, and blood pressure. There is extensive research on other vasoactive substances including catecholamines, renin, angiotensin, adrenal steroids, hypothalamic hormones, and vasopressin.

Of all the hormones known to influence cardiac growth and function, the thyroid hormones have been studied most widely. Recently, research was initiated on the mechanisms of cardiac enlargement and on the mechanism by which thyroid hormones affect not only protein synthesis but also the type of contractile protein synthesized. Future research will include investigation of how maternal thyroid disease or deficiency may impact on cardiac development of the fetus.

The observation that women before menopause have less heart disease than men, combined with the observation that women have a higher level of circulating high density lipoprotein (HDL) than men, has led to a focus on sex hormones, especially estrogens, and their role in atherosclerosis. In order to better understand how sex hormones affect atherosclerosis, researchers are investigating the effects of estrogen, testosterone, and progesterone on blood clotting, lipoproteins, apoproteins, arterial reactivity, and the ability of the arterial cells to form plaque. Research focusing on the pathogenesis of cardiomyopathies includes investigation of adrenal medullary hormones and potential interrelationships among estrogens and progesterone, immunity-mediating cells, and resistance to myocarditis.

Efforts are under way to understand the biologic mechanisms by which diabetes contributes to cardiovascular disease. Since the diabetic heart is prone to chronic failure, researchers are examining various aspects of the contractility of the heart, including the underlying contractile protein metabolism and the metabolic energy utilization that underlie the heart's contraction. Cardiovascular disease in diabetes is often associated with blockage of arteriosclerotic arteries by blood clots. Studies focusing on abnormal blood clotting relate particularly to the platelets' abnormality and hypersensitivity to aggregation in human and animal diabetes, and to potential agents that may inhibit such hypersensitivity.

In the area of lung diseases, efforts, for the most part, concentrate on the effects of hormones on the maturation of fetal lung. Neonatal respiratory distress syndrome (RDS) is a condition in which an infant's lungs have not developed sufficiently before birth and therefore are unable to process enough oxygen for the baby's needs even when pure oxygen is given. A variety of hormones influence the maturation of fetal lung. Hormones which accelerate fetal lung maturation are now being used clinically in an attempt to prevent RDS of the newborn. The hormonal regulation of pulmonary surfactant synthesis is of central concern because studies have shown that infants who die from RDS are deficient in pulmonary surfactant. A clinical trial supported by the NHLBI has shown that the overall incidence of neonatal RDS is lowered significantly by maternal administration of corticosteroids. However, the decrease in neonatal RDS appeared to occur only in singleton female offspring. Male fetuses did not benefit from the steroid treatment. This apparent sex difference in response of the fetal lung to corticosteroids is being examined further. Another hormone, thyroxine, is a potent accelerator of surfactant synthesis and probably works by an independent mechanism. Clinical trials are now being planned to test the hypothesis that corticosteroids given in combination with thyroid hormone may effectively stimulate lung development.

Pregnancy complicated by maternal diabetes mellitus poses substantial difficulties for both mother and fetus. In addition to the problems encountered by the mother with respect to aggravated impairment of carbohydrate and lipid metabolism, the offspring is at increased risk for multiple problems, including abnormal growth and neonatal respiratory distress syndrome. Studies of the effects of insulin on lung maturation and surfactant synthesis are currently under way. In other studies, lung cells are being used to investigate the influence of insulin and steroid hormones on the lung. Infants of diabetic mothers have about a 10 percent risk of developing RDS despite the fact that they have substances in the amniotic fluid that indicate lung maturity. New research has led to the development of a very specific test for the surfactant protein in amniotic fluid. Preliminary results indicate that this test might provide a more sensitive and accurate predictor of RDS in these infants than present tests. The clinical usefulness of the procedure is currently being evaluated.

In the area of blood diseases, the NHLBI has several ongoing activities. One area of research involves the hormone erythropoietin which stimulates the bone marrow to produce red blood cells and serves as a link in one of the feedback circuits that adjusts the supply of oxygen to the cellular needs of the body. Several illnesses can be related directly or indirectly to abnormalities in erythropoietin production or action. Studies include research on the mechanism of erythropoietin formation in the kidney and in the liver. These studies involve isolation of genetic messenger molecules involved in the synthesis of the hormone. Investigators are attempting to identify and clone the cellular receptor for erythropoietin. Also, with the use of monoclonal antibody techniques, an effort is underway to improve the methods for purification of erythropoietin. In addition, scientists are attempting to develop improved methods to assay the hormone. If they are successful, a sensitive assay would be readily available for the diagnosis and management of several diseases involved.

Efforts are also under way to study the use of a vasopressin derivative, 1-desamino-8-D-arginine-vasopressin (DDAVP) in a newly described type of hemophilia: platelet-type von Willebrand disease. DDAVP can be effectively substituted for blood products in persons with other types of von Willebrand disease or with mild classic hemophilia (Factor VIII deficiency), when surgery is anticipated. This derivative could provide a safe alternative to the use of blood products.

Intramural Program

In its intramural program, the NHLBI supports endocrine and endocrine-related research including studies of the influence of catecholamines and steroids on high blood pressure, prevention of glandular failure in transfusion-dependent anemias, and basic studies of hormone actions.

Research focusing on catecholamines is directed toward an understanding of the basic biochemical and physiological processes regulating secretion of norepinephrine and epinephrine, and toward development of more effective treatment of hypertension that may result from overproduction of catecholamines.

Studies also include investigations of the correlation between changes in calcium ions (an integral factor of hormone secretion) and secretion of catecholamines. It is thought that blood pressure is elevated, in part, following elevations of the calcium content of muscle cells of blood vessels. Other studies assess the release of catecholamines by the autonomic nervous system in hypertensive disorders.

Another contributor to high blood pressure is an overproduction of the steroid aldosterone. Studies of the control of aldosterone secretion by the adrenal gland are under way to better understand idiopathic aldosteronism, in which both adrenal glands increase production of aldosterone. Overproduction of aldosterone is studied in patients by computerized x-ray scanning, magnetic resonance imaging, and hormonal analysis of blood from both adrenal veins, and by administration of radioactive chemicals preferentially taken up by adrenal tissue.

Repeated blood transfusions for certain types of chronic, transfusion-dependent anemias can lead to deposition of iron in endocrine glands and loss of function or glandular failure. Current studies include evaluation of desferoxamine, an iron chelator, as a means to remove the excess iron from critical body tissue and restore normal function. The use of desferoxamine as a prophylactic agent to prevent occurrence of endocrine deficiency also is being evaluated.

NATIONAL INSTITUTE OF DENTAL RESEARCH

Extramural Research

The National Institute of Dental Research (NIDR) supports studies of the causes, treatment, and prevention of disabling oral diseases and conditions. The majority of endocrine-related studies are supported by the extramural programs. Bone remodelling associated with craniofacial growth and development, tooth eruption, orthodontic tooth movement, and correction of congenital and acquired anomalies involve controlled bone formation and resorption. Localized bone loss also occurs in periodontal disease. These processes are influenced by classical hormones and newly identified growth factors. Investigators are defining the roles of hormones such as parathyroid hormone, calcitonin, thyroxine, estrogens, glucocorticoids, vitamin D, prostaglandins, epidermal and platelet derived growth factors, and bone morphogenic protein in controlling bone metabolism.

Interactions between hormonal and genetic factors are important in cleft palate induction. Glucocorticoids are essential for normal palatal development, but in pharmacologic doses they can cause cleft palate. Genetically susceptible strains of mice are being used to locate the genes responsible for susceptibility and to describe the biochemical mechanisms leading to cleft plate formation.

The alleged increase in periodontal disease and impaired wound healing associated with diabetes mellitus continues to receive attention. Altered collagen metabolism, leucocyte dysfunction, modified oral microflora, effects of bacterial toxin, and changes in immunologic status are being studied as mediating factors in diabetic animals and human subjects.

Studies on neuroendocrine factors (endorphins) in post-surgical pain and placebo-induced analgesia will continue to provide rational approaches to pain management.

Intramural Research

Much of the endocrinology research conducted by intramural scientists complements that supported by the extramural programs. The basic causes of diabetes are being sought. Viruses which infect insulin-producing cells cause diabetes in animals. The possibility that viral infections of the central nervous system also can lead to diabetes is being investigated. The bone inductive protein, osteogenin, isolated from bone matrix, is being identified and characterized, and the influence of diabetes on its properties is being assessed.

Corticotropin-releasing factor induces elevated plasma endorphin levels and reduces post-operative pain, suggesting that endogenous pain inhibitory systems may be activated without the liabilities of present pharmacologic agents. Neuroendocrine control of salivary gland function will continue to receive priority in view of the importance of saliva to oral health.

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

The area of neuropeptide research has become synonymous with neuroendocrinology since the most prominent substances under investigation (e.g., vasopressin and endorphins) clearly are released into the blood stream for action at distant sites. The presence of neuropeptides in the central nervous system and in other regions of the body has been known for many years; however, knowledge of their specific identification and the roles they play in regulating physiological functions is of recent origin. With the advent of new technologies, such as radioimmunoassays and immunocytochemical techniques, several neuropeptides have been localized and their associated neuronal pathways identified in the central nervous system, peripheral nervous system and the gastrointestinal tract. Further progress was made when the modes of their biosynthesis, secretion, degradation, translocation, etc., were discovered.

In the past five years, two major findings in endocrinology have had an enormous impact on neurological research. First, the discovery that at least 50 recently described peptide hormones are also present in brain and secreted from neurons has altered basic concepts in neurobiology and is leading to the greater development of new pharmacologic strategies for treating neurological disorders. Second, the development of molecular genetic methodologies has rapidly advanced studies of these new hormones in the brain and provided the foundation for the development of gene therapy for particular neurotransmitter systems in the central nervous system.

The importance of the discovery of 50 new neurotransmitters in the brain is highlighted by the fact that all of our currently available drugs for treating neurological diseases were developed by studying only the five originally discovered neurotransmitters. Through the development of drugs via these 50 recently discovered peptide neurotransmitters, we can expect to increase greatly the number of drugs used to treat neurological diseases. Many new peptides are currently being identified in the brain using chemical techniques as well as new recombinant DNA methodologies. While many studies are at the descriptive stages of investigation, the development of a number of new pharmaceutical strategies already seems likely.

Extramural Research

Although the field seems to be well advanced in describing neuropeptides physically and biochemically, little is known yet about the role they play in disorders of the nervous system. Neuropeptides have been implicated in sensory conduction mechanisms, such as, pain; neurological disorders, e.g., Parkinson's disease, Huntington's disease, Alzheimer disease, vasospasm, epilepsy, etc.; and behavioral manifestations, e.g., learning, memory, feeding behavior, temperature regulation, sleep disorders, circadian rhythms, etc. Intensive and concerted efforts need to be mounted to search for the cause or causes of neurodegenerative diseases. Additionally, much research may be anticipated on one neuropeptide, cholecystokinin, which is involved in appetite control.

Adrenal steroids, whose secretion is primarily controlled by the hypothalamus and the pituitary, not only turn off the corticotropic releasing hormone in the hypothalamus but affect brain excitability as well. Recent evidence indicates that the sex hormones have major effects on brain development. Future studies will involve the anatomical localization of a large number of neuroactive peptides, the mechanisms controlling their production and release, and their multiple sites of action. An area of great interest involves the activity of neuropeptides as cotransmitters or modulators in the neural synapse, and the mechanisms of their metabolism and degradation.

Much additional work can be anticipated in unravelling the action of one neuropeptide, substance P, in pain mechanisms. The use of agents to counter substance P may be important in the future in controlling pain. Similar extensive studies may be expected concerning the mechanism of action of the naturally-occurring opioids which are critical to the body's self-control of pain. The identification of opioid receptors has engendered a deep interest in discovering similar receptors for other peptides with a view to uncovering the pharmacologic functions these substances play in health and disease.

Intramural Research

Intramural scientists in the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) have identified eight neuropeptides in the brain: alpha-melanocyte stimulating hormone (MSH), secretin, motilin, ranatensin, thymosin, alpha- and beta-endopsychosin, and a peptide related to pancreatic polypeptide which subsequently was named neuropeptide Y. These peptides are now being studied, and the results indicate that at least three of these compounds may lead to important new drugs for the treatment of neurological disorders. Alpha-MSH has been shown to enhance cognitive function in rats and humans and has been reported to improve cognitive performance moderately in persons with Alzheimer disease or mental retardation. In a collaborative effort between Upjohn Company and the Institute's Unit on Neuroendocrinology, a number of super-potent alpha-MSH derivitives are being tested as cognitive enhancers. Alpha- and beta-endopsychosin are two new neuropeptides which bind to the same receptors in brain to which the street drug phencyclidine (PCP or angel dust) also binds, producing a psychosis similar to schizophrenia. The fact that the endopsychosin peptides produce the same behavioral and physiological effects as PCP suggests the possibility that a pathology of the neuronal systems which produce endopsychosin peptides in the brain could be involved in producing psychoses.

Recent findings indicate that many of the shortcomings of antihypertensive drugs are due to their failure to block the actions of neuropeptide Y. Intramural scientists are exploring the role of neuropeptide Y in hypertension and sympathetic disorders. The recent development of implantable pressure transducers coupled with an infusion pump permits the automatic infusion of hormones to regulate blood pressure on a minute to minute basis and may allow patients with severe sympathetic disorders to lead a longer and more normal life.

A number of other peptide hormones in the brain appear to be extremely important in neurological disease and are currently under investigation in intramural laboratories. Recent investigations indicate that the peptide, somatostatin, is depleted in regions of the brain affected by Alzheimer disease. These experiments are focused on the cognitive effects of depleting or replacing somatostatin in humans. Investigations in other NINCDS laboratories are exploring the role of somatostatin in an inherited form of Alzheimer disease.

The endorphin family of peptides is an extremely important class of hormones in the brain not only because they are central mediators of analgesia but also because they have a number of other critical functions. Recent investigations have demonstrated the important roles of the endorphins in mediating functions of the immune system. One NINCDS intramural scientist has recently found that endorphins may play a role in the etiology of insulin-induced hypotension. Another is studying the role of these opioid brain hormones in central vascular disorders and ischemia.

Intramural laboratories are also studying the normal and pathological cell biology of endocrine tumors. Scientists are examining the mechanisms of hormone secretion from prolactinoma tumor cells. One researcher is studying the mechanisms of action of the peptide hormone, thyrotropin releasing hormone, on calcium channels and secretions of prolactin from pituitary tumors. In addition, another intramural scientist is studying the regulation of peptide gene expression in pituitary tumor cells using recombinant DNA methodologies. Other NINCDS researchers are comparing gene expression in normal pituitary and pathological tissue removed from patients with Cushing's syndrome, and one intramural scientist is attempting to develop a non-surgical method for treating Cushing's disease by conjugating corticotropin releasing factor to a cellular toxin which will then selectively bind to and kill the corticotroph tumor cells.

It is quite clear from these initial experiments that important new drugs for the treatment of neurological disorders will be developed by manipulating the peptide hormone systems of the brain. Areas of particular importance for future research on neuropeptide hormones include: (1) identification of additional neuropeptides in the brain; (2) exploration of the mechanisms of regulation of gene expresion for peptide hormones including detailed studies of the enzymes and processes involved in the synthesis, secretion, and degradation of hormones in brain; (3) studies of neuropeptide receptors and the post-synaptic mechanisms of action; (4) identification of physiological and pathophysiological roles of the neuropeptidergic systems; (5) synthesis of drugs which are resistant to degradation and pass the blood-brain barrier, and which interact with peptide gene expression, peptide biosynthetic processing enzymes, peptide receptors and peptide degradative enzymes; and (6) development of techniques for neuropeptide gene transplantation into mammalian endocrine cells and neurons.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

An important sub-division of endocrinology-related research addresses the range of substances known as lymphokines. These powerful substances are produced and released into the bloodstream by specific types of lymphocytes and macrophages and are capable of stimulating or otherwise influencing other cells in the immune system. It has become clear that these agents are essential for immune responses and the generation of host defense mechanisms. By virtue of its reponsibility to support research on the immune system as an organ system and the mechanisms of immunoregulation, the National Institute of Allergy and Infectious Diseases (NIAID) foresees significant developments forthcoming in the field of lymphokine research.

Cloning of the genes for some of these important substances already has led to the production of these substances in useful amounts through recombinant DNA technology. It can be anticipated that the cloning of additional genes and production of more of the substances will occur in the near future. The production of large quantities of pure materials will facilitate the research aimed at such important issues as the regulation of biosynthesis, identification of receptors, a full characterization of action and target cells, the mechanisms of action, and the use of agonists and antagonists. An expansion of current preliminary clinical trials can be anticipated as well as attempts to modulate several diseases that have an immune basis. Prominent among current trials is the use of lymphokines, alone and in combination with other drugs, in treatment regimens for the Acquired Immunodeficiency Syndrome (AIDS).

It can be anticipated that lymphokine research will lead to a better understanding of immunoregulation and clinically useful methods for modulating immune responses in the treatment and prevention of a wide range of diseases.

NIAID scientists recently demonstrated that two neuropeptides have effects upon the proliferation and differentiation of human B lymphocytes; studies will continue on such interactions between the immune, endocrine and nervous systems which have potential clinical importance.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

The mission of the National Institute of General Medical Sciences (NIGMS) is to support fundamental biomedical research that undergirds the missions of the categorical institutes. The research is undifferentiated, basic, and investigator-initiated. This research contributes broadly to our understanding of the normal biologic processes in man and the pathological mechanisms of disease.

Although the Institute does not directly support research on endocrinology, the research supported in the Institute's Genetics Program is broad in scope, and has provided a good part of the biotechnology and, more important, hypotheses and concepts now used in endocrinology research. Recombinant DNA techniques, developed by NIGMS grantees, have led to increased knowledge about the genes determining the structure of several human hormones, including growth hormone, insulin, and epidermal growth factor. These hormones can now be produced in significant quantities for use in treatment of diseases previously dependent on substances concentrated from live biologic material.

Basic research studies on peptide hormones and their natural inhibitors are supported by this Institute. Beta-endorphin-(1-27) is a naturally occurring peptide found in pig, rat, and horse pituitary glands and in the brain. This peptide consists of the first 27 amino acids of beta-endorphin, which itself is 31 amino acids long. A NIGMS grantee recently showed that human beta-endorphin-(1-27) inhibits the analgesia that normally is produced by either beta-endorphin or by etorphine, a potent analogue of morphine. Because of its properties, it was named beta-endorphin inhibiting peptide. Its inhibition of analgesia is dose-related and effective during the entire time-course of analgesia. Quantitative laboratory analyses of the characteristics of the inhibition indicate that it competes with analgesic substances. Human beta-endorphin inhibiting peptide is four to five times more effective than the drug naloxone in inhibiting etorphine-induced analgesia. Naloxone is used clinically for the reversal of narcotic depression, and in the treatment of acute opioid overdosage. The future ramifications of these results are being investigated.

Investigators also have examined the immunosuppressive activity of prednisolone. Lymphocytes seem to be relatively insensitive to prednisolone before they are activated, but become extremely sensitive to the drug's inhibitory effect immediately following their activation. This sensitivity decreases with time and disappears after about 30 hours. These results are consistent with the hypothesis that prednisolone exerts its inhibitory effect by specifically interfering with the early phase of cell activation, prior to any significant increase in DNA synthesis by the cells. Considerably more research, however, will be needed before the mechanisms of prednisolone effects can be understood fully.

Cells respond to chemical agents such as drugs, hormones, and neurotransmitters via a two-step process. These agents act as extracellular signals by first binding to a receptor in the cell membrane. The signals are then transformed to intracellular signals in the form of cyclic AMP. Members of a family of proteins called G proteins serve as important parts of this cell information communication system. The G proteins act as coupling or transfer agents to transmit information from receptors to proteins that then cause a cellular response. Institute grantees are using a wide variety of state-of-the-art approaches to better understand the functioning of this family of proteins and their relationships to hormones. Studies have shown that the entire family of G proteins share a common amino acid sequence implying that they were all derived from some common genetic precursor at some point in the distant past. The techniques are now in hand for elucidating the entire signal transduction process in both normal and abnormal cells. In addition, this type of approach can be applied to other, less well-understood receptor systems such as the alpha-adrenergic receptor, the acetylcholine receptor, the serotonergic receptor, the dopaminergic receptor, and the opiate receptor.

The applications of this research are many. Understanding the function of the family of G proteins and the signal transduction process will provide a potential means to correct deficiencies in this system which occur in certain disease processes. Knowledge of the structural requirements for the receptor itself and of the process by which it binds to other chemical agents will permit the design of more specific, and thereby potentially less toxic, drugs and hormone analogues.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Extramural Research

The National Institute of Child Health and Human Development (NICHD) supports a substantial amount of research in the area of reproductive endocrinology. Significant progress has been made toward the solution of some of the problems of infertility. This includes studies of anovulation and hyperprolactinemia. In addition, basic research has identified new leads for the development of more acceptable means of fertility regulation. For example, Institute-supported projects have identified three previously undiscovered proteins that have significant potential for fertility regulation--oocyte maturation inhibitor, inhibin, and follicle regulatory protein. Future plans call for increased efforts aimed at alleviating or treating unexplained infertility, polycystic ovarian disease, dysmenorrhea and endometriosis as well as continued basic research and clinical trials of compounds which can be used for new means of fertility regulation.

Research in developmental endocrinology also is provided substantial support by the Institute. Studies related to the achievement of implantation of the embryo are under way, and expanded research on requirements for formation of a new embryo, its continued health and survival, and its successful implantation needs to be encouraged.

In addition, the Institute supports studies of hormonal influences on growth and development, studies of growth factors, and studies of the development of the hypothalamic-pituitary axis in relation to the thyroid, adrenal glands, and gonads. Studies by NICHD grantees have shown that injections of biosynthetic growth hormone produce linear growth acceleration in human growth hormone-deficient children as well as in short children who are not hormone-deficient. Studies have documented the effect of growth hormone-releasing factors in growth hormone-deficient children and adults. The gene responsible for steroid 21-hydroxylase deficiency recently has been identified by Institute grantees. Anti-insulin antibodies (AIA) are being studied at diagnosis and during development of insulin dependent diabetes mellitus in children. The data confirm that AIA are present at onset and develop shortly before the onset of frank symptoms.

Future plans in developmental endocrinology call for an expansion of research on the role of growth factors in fetal life, especially their ontogenesis, receptors, biologic responses, and their relation to oncogenes. More basic studies will also be encouraged on hormonal control of gene expression with emphasis on investigation of molecular mechanisms. In addition to elucidating the roles played by various growth factors during fetal growth and development, emphasis will be placed on uncovering their roles in postnatal life. Research on the roles of receptors in human disease will be emphasized. More basic studies of growth hormone-releasing factor need to be pursued along with a possible multicenter clinical trial of GRF and GRF analogues. A major challenge for the future is to expand studies of the functions of neuropeptide hormones that are being discovered in the brain. Investigations of puberty and growth need to be expanded and studies of the teratogenic effects and subtle defects produced by diabetes in pregnancy need to be increased.

Intramural Research

Studies of developmental endocrinology conducted by the intramural program of the NICHD include the endocrine concomitants of normal and abnormal human growth, development, and differentiation. Specific areas of study include the mechanisms underlying the initiation of puberty; the regulatory physiology and biochemistry of the glycoprotein hormones; the roles of sex steroid hormones, growth hormone, and other growth factors in bone growth; and the physiology and biochemistry of the action of hypothalamic releasing hormones. Clinical research on male and female reproductive disorders is also a major interest. In research on the use of estradiol for optimal growth in girls with Turner's syndrome, recent findings suggest that ultimate stature may be improved with low dose estrogen treatment and that the currently popular regimen of a much higher dose may actually be harmful and reduce ultimate height. If this finding is confirmed, it represents an important advance in the treatment of this disorder. One of the new insights relevant to the reproductive process centers on findings in infertile men. Recent work suggests that proteins coating the head of sperm serve as the recognition site for the sperm-egg interaction. Several of these proteins have been isolated, and it is now possible to map the distribution of some of these on sperm. In a high proportion of men with idiopathic infertility, the distribution of these proteins is abnormal. This finding may be important in clarifying the mechanism underlying idiopathic male infertility and suggests an approach to rational therapy.

In the area of reproductive endocrinology, current research is focused on the mechanisms controlling hormone secretion and action, with particular reference to hypothalamic-pituitary hormones and their receptor-mediated responses in endocrine target cells. This work includes the analysis of structure-function relationships displayed by peptide and glycoprotein hormones, and studies on the receptors and actions of hypothalamic peptides (GnRH, somatostatin, CRF and GRF), angiotensin II, ACTH, prolactin, and gonadotropins. The characterization and isolation of peptide hormone receptors, the clarification of plasma-membrane-related messenger systems, and further elucidation of the control of steroidogenesis and glycogen synthesis are major goals. Some of this research involves analyzing physiological and pathological aspects of the renin-angiotensin system with emphasis on the role of angiotensin II in the regulation of aldosterone secretion and circulatory homeostasis. These studies are relevant to understanding the pathogenesis and treatment of certain types of hypertension. In other work, a new highly sensitive immunoradiometric assay method is being developed that permits direct measurement of human chorionic gonadotropin (hCG) in urine and other biologic fluids. This method should provide a substantial advantage over currently available methods for the monitoring of early pregnancy loss and the management of certain hCG-secreting tumors.

NATIONAL EYE INSTITUTE

The National Eye Institute's (NEI) support for research in endocrinology is related primarily to ocular pathology caused by diabetes mellitus. Of the estimated 20 million diabetics in the United States, approximately 4 million are believed to have vision problems caused by diabetes. One form of diabetic complication--diabetic retinopathy, in which the retina is damaged by breaks in small retinal blood vessels and resulting hemorrhages--is the leading cause of new cases of blindness in middle-aged individuals. Because of this, the NEI continues to emphasize basic and clinical research aimed at obtaining new information relevant to the prevention, diagnosis, and treatment of diabetes-related eye problems in its extramural and intramural research programs.

Extramural Research

One recently instituted clinical study, the Sorbinil Retinopathy Trial (SRT), is focusing on the prevention of diabetic retinopathy through the administration of the drug sorbinil, an inhibitor of the enzyme aldose reductase. Aldose reductase has been shown to play a key role in triggering the vascular, neural, and lens complications of diabetes. This multicenter study, involving 600 insulin dependent diabetics, is being conducted in collaboration with Pfizer Incorporated, the pharmaceutical company which developed the drug. The SRT will test whether sorbinil can prevent or slow the development of diabetic retinopathy in people who do not yet show significant signs of this disease. Recruitment of patients for this study is still in progress.

Another NEI-supported clinical trial, the Early Treatment Diabetic Retinopathy Study (ETDRS), is designed to test the effectiveness of argon laser treatment in people whose diabetic retinopathy has not progressed far enough to pose an immediate risk of blindness. One of the first signs of diabetic retinal involvement is a blurring of vision caused by macular edema. This condition is a result of the swelling of the central visual area of the retina due to the leakage of fluid into the retinal tissues.

Recruitment for this study has now ended. Initial findings indicate that focal argon laser treatment, in which the laser is used to coagulate only tissue suspected of leaking fluid into the macula, decreased the amount of visual loss, increased the chance of visual improvement, decreased the frequency of persistent macular edema, and caused only minor visual field losses when compared to an untreated group. These findings have led the ETDRS investigators to recommend foveal photocoagulation treatment in all eyes with significant macular edema and nonproliferative retinopathy.

The Diabetic Retinopathy Vitrectomy Study (DRVS) is another treatment evaluation study comparing early vitrectomy with deferred vitrectomy in individuals with diabetic retinopathy who have suffered a vitreous hemorrhage. Vitrectomy is a surgical procedure for removing the blood which leaks from abnormal retinal vessels into the clear jelly-like material (vitreous) inside the eye. This may induce scar tissue formation which can cause retinal detachment and lead ultimately to permanent vision loss or blindness.

Investigators have found at two-year follow-up examinations in the DRVS that a higher percentage of eyes undergoing early vitrectomy recovered a 20/40 visual acuity (driving vision in most states) than did the eyes in which the treatment was deferred in hope that the hemorrhage would clear on its own. The percentage recovering 20/40 vision was even higher in Type I (juvenile onset) diabetics. The investigators have concluded that early vitrectomy can improve chances of long-term recovery of good vision in some eyes.

A decade of basic research on the formation of diabetic or "sugar" cataracts through the action of the enzyme aldose reductase has not only paved the way for the development of aldose reductase inhibiting drugs such as sorbinil, but has also opened other avenues of investigation in the role of aldose reductase in a variety of diabetic complications. Scientists are attempting to determine the physical, chemical, kinetic, and structural properties of aldose reductase. This work should lead to a more precise understanding and control of the pathological effects observed in diabetes. The knowledge gained should also be useful to those who are designing anti-cataract drugs by allowing them to choose suitable modifications of existing drugs or to select other drugs that might be more specific for aldose reductase and also have fewer undesirable side effects.

One NEI grantee is investigating the biochemical mechanisms which lead to the formation of diabetic cataracts in humans. Aldose reductases are also being purified from human tissues to determine their kinetic, structural, and immunological properties, again with the aim of developing more specific aldose reductase inhibitors for the prevention of diabetic cataracts.

Other basic research is being directed toward developing an understanding of the pathology associated with diabetic retinopathy. Researchers are attempting to characterize the cellular properties of retinal microvessels that underlie their vulnerability in diabetes mellitus. The enhanced permeability and thickening of the basement membrane (a supporting structure on the outside of the vessel wall) of these retinal vessels in diabetes is of particular interest in this study.

Permeability of the blood-retinal barrier that is formed by the various cells of the retinal blood vessels and the retinal pigment epithelium (endothelial cells, pericytes, and retinal pigment epithelial cells) is currently under investigation. The morphologic changes in this barrier in diabetes also are being compared to the normal morphology of the barrier.

Investigators are attempting to develop a noninvasive vision technique that can be used prior to a breakdown of the blood-retinal barrier to monitor the efficacy of medical and surgical treatment and to provide diagnostic and prognostic indicators for the treatment of diabetes and its retinal complications.

Intramural Research

Investigation of the role of aldose reductase in the development of diabetic ocular pathology continues to be a major research activity of the NEI. The events leading to the formation of diabetic cataract and the role that aldose reductase plays in its formation are currently being studied. The relation of aldose reductase to diabetic keratopathy and pupillary changes is also being investigated.

Intramural scientists are growing bovine, canine, and human mural and endothelial cells from retinal capillaries in diabetic and normal states to assess the role of aldose reductase in the development of diabetic retinopathy. Earlier NEI studies have demonstrated a diabetic-like thickening of retinal capillary basement membrane in galactose-fed rats which could be prevented by two structurally different inhibitors of aldose reductase.

Isolation and characterization of the gene for aldose reductase are under investigation. The goals of this research project are to utilize the structural information obtained to selectively inhibit the aldose reductase gene in target tissues and to investigate the level of gene expression of aldose reductase in experimentally-induced diabetic and galactosemic animals.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

The endocrine system has complex interactions with the environment. Many environmental cues (visual or olfactory) are important triggers for endocrine responses; the endocrine system also is modulated by chemicals in the environment. Numerous toxicological studies have reported adverse effects of environmental chemicals on functions under the control of the endocrine system; the molecular mechanisms underlying these effects, however, are as yet largely unknown. In support of the goal to understand toxic chemical/endocrine interactions, the National Institute of Environmental Health Sciences (NIEHS) supports a broad spectrum of research examining the influence of chemicals on the endocrine system.

Extramural Research

One of the consequences of diabetes is a change in the way the liver metabolizes environmental compounds. NIEHS grantees have begun a new study relating the altered hepatic metabolism to the susceptibility of diabetics to chemical toxicants and carcinogens encountered in the environment. An understanding of these relationships is important to those who oversee the care of diabetic patients and to individuals interested in the hormonal regulation of biochemical processes involved in metabolism.

Adverse effects of chemicals on reproductive function have been reported frequently in animals and humans; the mechanisms for such untoward effects, however, are largely unknown. Scientists are studying how environmental chemicals interact with the reproductive endocrine system. Preliminary data indicate that some environmental chemicals (flavone and morin hydrate) compete with estradiol *in vitro* for binding to the rat uterine estrogen receptor. In addition, the hydrocarbon metabolites, 1-naphthol and 9-phenanthrol, act directly on isolated rat Leydig cells to inhibit testosterone secretion.

Researchers are currently examining the non-pesticidal biologic effects of chlorinated hydrocarbons in mammalian systems. As a part of these investigations, the contaminants in methoxychlor are being examined as to their estrogenic activities. Out of 16 compounds identified, two (methoxychlor and dehydro-dechloromethoxychlor) were proestrogens and the mono- and bis-phenolic derivatives of these two compounds were estrogenic. These findings demonstrate that it is currently impossible to determine *a priori* (based on structure) whether a given compound will have estrogenic activity. The results from these studies on the biochemical events may lead to methods of detecting potential toxicity too subtle for early detection by conventional tests.

The mechanisms of action of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) remain perplexing. Preliminary studies to elucidate the mechanisms of TCDD toxicity in cell cultures suggest that exposure of the whole animal is required for toxicity. These and other data have provided a basis for the hypothesis that TCDD may manifest its toxicity through its action on a variety of major hormones. Scientists are examining the influence of TCDD on hormonal balance following low doses of this chemical and have shown that TCDD administration in rats results in significantly decreased serum throxine and insulin levels. Preliminary data have suggested that these hormonal effects may be due to changes in prolactin levels and activity. Future studies may clarify the role of prolactin and hormones in general in the mechanisms of TCDD toxicity.

Other NIEHS grantees are attempting to relate two of the recognized effects of chlorinated hydrocarbon pesticides (neuro- and reproductive toxicity) to neuroendocrine changes in the exposed animal. Using short-term exposure to chlordecone, they have shown a direct effect of chlordecone on neuroendocrine parameters and sexual behavior. In addition to providing mechanistic information on the toxicity of such chemicals, these studies may provide a basis for the inclusion of neuroendocrine parameters in the neurotoxicity evaluation of chemicals.

Intramural Research

Infertility may be caused by environmental chemicals although actual environmental effects on fertility have been hard to measure, in part because the existing epidemiologic methods are insensitive. Scientists within the NIEHS are developing several approaches to measuring fertility. In one, they are analyzing daily urine specimens from women of reproductive age. The samples, from both pregnant and non-pregnant cycles, will be analyzed for metabolic products of estrogen and progesterone, which reflect the function of the ovary and the corpus luteum. This analysis will permit characterization of the physiological differences between fertile and non-fertile cycles in a way that has not been possible before. This may lead to improved methods for detecting environmental disruptions of human fertility in exposed populations.

Another aspect of this research involves measurement of early pregnancy loss. The risk of spontaneous abortion is known to be affected by environmental exposures. It is not known, however, how much more pregnancy loss occurs before pregnancy is recognized or how sensitive this early loss might be to environmental exposures. To explore these questions, NIEHS researchers are conducting a prospective study of 230 normal women who are trying to become pregnant. These women collect daily urine specimens that are analyzed for human chorionic gonadotropin, a pregnancy hormone produced about seven to eight days after conception. The risk of early loss in this group of women will be analyzed in relation to alcohol consumption, cigarette smoking, and other exposures common among these volunteers.

NIEHS intramural scientists are directing a major effort toward understanding the structural basis of estrogenic environmental chemicals, or those chemicals which possess the biologic activity of the female sex hormone estrogen. The environmental distribution of these compounds has two major sources: synthetic chemicals introduced as by-products of civilization and naturally-occurring estrogens found in numerous plants as well as molds that infest stored crops. Elucidation of the molecular structure common to this class of compounds is crucial in the prediction of those chemicals that will exert estrogenic effects on exposed humans. This area of research can be applied directly to problems of public health concern, such as the reports of premature sexual development in Puerto Rican children. Research at the NIEHS on the pharmacology and structural biology of environmental estrogens has been instrumental in elucidating the toxicological principles that must be followed in dealing with this potential human health problem.

Further studies at the NIEHS on abnormal development and cancer induced by estrogens have resulted in new insights into the mechanism of action of estrogens, including the propensity of these compounds to permanently alter cell differentiation at the molecular level. This provides new therapeutic strategies to prevent cancer in estrogen target tissues such as the breast, cervix, and uterus, as well as different approaches to the environmental monitoring of these compounds. The studies on abnormal development in estrogen-exposed mice also have provided an animal model for DES-exposed humans that has had clinically relevant predictive powers. Continued comparisons between well-characterized experimental models and DES-exposed human cohorts should permit development and validation of hypotheses generally applicable to risk assessment.

Peptides can have profound effects in human reproductive functions, and several peptide hormones play a key role in fertility and sterility. NIEHS intramural investigators are analyzing the presence and possible role of peptides in human follicular fluid, a project that is being carried out in collaboration with NIEHS grantees. The presence of angiotensin II, a peptide with potent vasoactive and steroidogenic properties recently has been detected. These intragonadal peptides may play a key role in the regulation of folliculogenesis, ovulation, and early pregnancy maintenance. Alterations in their function also may lead to menstrual irregularities and sterility.

Another way in which peptides can affect reproduction is exemplified by their role in contraception. Synthetic analogues of luteinizing hormone-releasing hormone (LHRH), an essential regulator of reproductive functions, are undergoing clinical trials in different laboratories to evaluate their potential use as contraceptives in men and women. Additional research in the intramural program is directed toward determining the mechanism and site of action of these peptides as well as any potential adverse effects they may possess. The particular neurotransmitters and intracellular messenger systems involved in the secretion of LHRH also are being characterized to gain some understanding of the intimate cellular and molecular mechanisms modulating the secretion of this peptide.

NIEHS laboratory researchers are evaluating the actions of receptors for toxic halogenated aromatics and estrogenically-active chemicals (including 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), structurally-related polychlorinated dibenzodioxins and dibenzofurans, 17a-ethinylestradiol, and zearalanol) in relation to the hepatotoxic potency of these compounds. These studies focus on receptor-mediated effects on gene expression critical to tumor production using the rat two-stage model for liver cancer. The objectives are to evaluate the quantitative relationships among dose of tumor promoter, receptor occupancy, critical changes in gene expression (such as oncogene activation), and histopathological alterations (including preneoplastic lesions and tumor incidence), and to investigate the time course of these changes. This approach should provide scientific data useful in classifying carcinogens according to mechanism of action and remove some of the uncertainty in estimating human risks of cancer following exposure to estrogenically-active compounds.

NATIONAL INSTITUTE ON AGING

The National Institute on Aging (NIA) supports research aimed at providing an understanding of the age-related changes in endocrine function, the mechanisms underlying these changes, and the impact of these changes on other physiological systems.

One of NIA's major priorities is increased understanding of endocrine factors in osteoporosis. Osteoporosis is a disorder in which bone mass and strength gradually decrease. The disease typically progresses silently, slowly over many years. It generally does not become clinically significant until later life, when it frequently becomes so severe that bones are highly susceptible to fracture. A fall or blow that would not injure a healthy person will cause a fracture in a person with osteoporosis.

In women, changes in estrogen levels following menopause appear to accelerate the rate of bone loss. The NIA is supporting research to determine how changes in levels of estrogens and other hormones cause bone loss. Estrogen therapy has been shown to be effective in blocking this accelerated bone loss, but many questions remain about who should receive treatment, and about what dosages, combinations with other agents, and routes of administration are most safe and effective.

Aging changes relating to the endocrinologic functions of vitamin D may be especially important in osteoporosis. Vitamin D is made in the skin as well as consumed in the diet. In a study supported by the NIA, scientists recently have found unequivocal evidence that the production of vitamin D decreases with age. In addition, this evaluation of the vitamin D blood levels in 150 elderly patients admitted to the hospital with bone fracture indicated a vitamin D deficiency in more than half the patients. Other research supported by NIA suggests that vitamin D supplementation may be helpful in treating osteoporosis, but further research is needed to determine the benefits of this approach.

One of the most frequently occurring disorders associated with old age is diabetes mellitus. The NIA supports research to determine the underlying mechanisms involved in diabetes and to develop improved methods of diagnosis and treatment.

There is considerable evidence that the effectiveness of insulin in controlling blood sugar is reduced with age. One study supported by the NIA indicates that physical activity may increase the effectiveness of insulin in older people. Other research supported by the NIA has demonstrated age-related changes in the pancreas that contribute to the development of diabetes. NIA-supported research has demonstrated that chronic impairments in control of blood sugar levels can lead to structural alterations in the nervous system leading to the neurologic problems of diabetics and possibly to the neurologic problems of the elderly as well. Since this is a potentially preventable cause of neurologic problems of the elderly, more research is especially needed on this problem.

FOGARTY INTERNATIONAL CENTER

The Fogarty International Center supports research fellowships for both junior foreign scientists to come to the United States and for senior U.S. scientists to conduct collaborative research in other countries.

In the past, Fogarty Scholars-in-Residence have contributed significantly to the study of problems in endocrinology. The following provides a few examples of anticipated collaborations between Fogarty Scholars and NIH intramural laboratories.

One Fogarty Scholar is collaborating with scientists within the National Institute on Mental Health on the study of receptors for neurotransmitters, many of which are neurohormones. This scientist expects to return for a second term as a Fogarty Scholar in 1986. His work has significance in the design of drugs to control deficiency of muscarinic receptors that are important for memory formation. His approach is through study of channels in nerve cell membranes that permit the flow of sodium and calcium ions. Calcium ions are known to be so-called "second messengers" that are important in mediating hormone action.

Another Fogarty Scholar is studying cyclic nucleotides and calcium ions, which are known to be essential for hormone action in many tissues. This scientist plans to return for a second term in 1986 to continue a collaboration with NCI scientists and to take part in organizing the 6th International Conference on Cyclic AMP and Protein Phosphorylation. This conference will be devoted to one of the central areas of endocrine research. In the search for effective drugs, understanding the mechanism of hormone action has great promise for control of endocrine disease.

One of the most significant causes of mental retardation in the world may be thyroid disease caused by lack of thyroid hormone during fetal life. Another Fogarty Scholar, who plans to return to NIH in April 1986, is now preparing action plans to combat preventable disability for the IMPACT program (an international initiative against avoidable disablement promoted by the United Nations Development Program, UNICEF, and the World Health Organization). In addition, another former scholar and an acknowledged expert on the basic causes of thyroid diseases is preparing a program of study involving a small group of thyroidologists to assist in the evaluation of thyroid status in developing countries and to assess practical methods for correcting the thyroid status of mothers in iodine deficient areas.

Yet another Fogarty Scholar whose work is concerned with embryological development, including the role of hormonal factor, plans to return to NIH in 1986. Much of this scientist's work has been concerned with the role of thyroid hormone in early development and in metamorphosis in amphibia.

DIVISION OF RESEARCH RESOURCES

Whereas the categorical institutes establish initiatives in various scientific areas, the Division of Research Resources (DRR) establishes multidisciplinary resources or centers to facilitate the efficient and effective conduct of biomedical and behavioral research. Preliminary assessment of the latest basic research discoveries regarding the safety and efficacy of new research techniques or modes of therapy occurs in Primate Research Centers, and further assessment of these new therapies occurs in General Clinical Research Centers (GCRC) prior to their use in health care settings. Primate Research Center improvements will contribute significantly to future advances in endocrinology research as have the following research accomplishments.

Animal Resources Program

Cellular Regulation of Hormone Secretion in Pituitary Cultures

Cell culture methods are being developed at the Oregon Primate Research Center that will allow more endocrine studies to be done *in vivo*, and fewer monkeys to be used. Savings in both money and animals promise to be substantial with the application of such techniques, and the collection of reliable data can be accelerated. Scientists are using monkey pituitary cells in culture to study the direct effects of progesterone, alone and in combination with estrogen, on prolactin production. From pituitary cells that are cultured from just one monkey, researchers can now carry out experiments simultaneously that earlier would have represented terminal studies in 72 animals.

Transplantation of Fetal Tissue in a Primate Model of Parkinsonism

Transplantation of competent cells to treat diseases that may result from acquired or inborn endocrine deficiencies represents an exciting area of research that will continue to be actively pursued in monkeys. The recent success of scientists in reversing the symptoms of Parkinson's disease in higher animals by implanting cells from monkey fetuses into the brains of afflicted monkeys is an example of such research. Scientists implanted dopamine-producing cells taken from the brain stems of 35- and 37-day-old rhesus monkey fetuses into the dopamine-deprived brains of adult monkeys. After two months of observation, the monkeys' abnormal movement showed marked improvement, and the dopamine levels in their bodies returned to normal.

Unique Primate Model for Gene Transfer/Gene Therapy Experiments

Using genetic manipulation, scientists have constructed a strain of *Herpes saimiri* virus which is found in squirrel monkeys, containing the gene for growth hormone. Cells infected with this strain of virus produce large amounts of growth hormone for long periods of time. Using this model, researchers may be able to engineer human herpesvirus vaccines for the correction of inborn errors of metabolism.

General Clinical Research Centers Program

Testing the Effects of Growth Hormone-Releasing Factor

Current studies suggest that most patients with growth hormone deficiency have an intact pituitary but have decreased secretion of the hypothalamic growth hormone-releasing factor (GRF). The administration of pulses of GRF every two hours results in a release of increased amounts of growth hormone in these patients, in some instances as great as those released by normal children. These findings support the hypothesis that the defect in most patients with growth hormone deficiency is within the hypothalamus and not in the pituitary. GRF or a long-acting analogue of it may thus provide a form of therapy to induce growth hormone release in children with growth hormone deficiency.

Calcitonin Treatment of Osteoporosis

Regular doses of a hormone involved in the prevention of bone decalcification appear to reverse the progressive thinning of bone that characterizes osteoporosis, a crippling disease that afflicts a quarter to a half of all women over age 45. This hormone, calcitonin, increased the bone mass of the majority of women with postmenopausal osteoporosis who participated in a recent study. It is not known whether calcitonin will continue to increase bone mass over the long term, but it does seem to prevent women from losing additional bone, a real step forward in the prevention and treatment of osteoporosis.

Steroid Aromatization

Aromatization is a key biochemical step in estrogen synthesis: its rate is increased in obese patients, and it may be altered in some men with coronary artery disease. Present methods for measuring this process *in vivo* require complete urine collections for five to seven days, with laborious extractions and crystallizations. A newly validated radiometric method involving periodic blood sampling can be completed over a two-day period, and it requires only relatively simple laboratory work. This new, speedier method will provide a key tool for investigating the link between alterations in estrogen metabolism and obesity, heart disease, and the risk of breast cancer.

Vitamin D Metabolism

Changes in the dietary intake of phosphorus can induce rapidly occurring, large, inverse, and persistent changes in the serum concentration of 1,25 dihydroxyvitamin D, the biologically active metabolite of dietary vitamin D. The results demonstrate for the first time that in humans the dietary intake of phosphorus can critically determine the serum concentration of 1,25 dihydroxyvitamin D by determining its production rate. Restriction and supplementation of the dietary intake of calcium respectively induce increases and decreases in the serum concentrations of this hormone, but these changes are transient and are smaller than those produced by variations in dietary phosphorus.

Prostatic Cancer

Prostatic cancer is a common disease in aging man. Its cause is unknown, but androgenic hormones secreted by the testes contribute to development of the tumor. It has been observed that brothers of men who developed the cancer before age 63 have a four-fold higher risk for this tumor than men of similar age in the general population, and that men at risk for the disease tend to have plasma levels of testosterone at the lower end of the normal range. Recent data indicate that men at risk for the cancer actually produce increased testosterone each day, but metabolized it more rapidly to metabolites of testosterone. These metabolites of testosterone are more potent than testosterone itself in stimulating growth of the prostate gland. Men at risk for development of prostatic cancer may have an inherited alteration of testosterone metabolism predisposing them to the occurrence of this tumor at a relatively early age.

3. RESEARCH TRAINING

Funding for research training is a critical element in the framework that supports endocrine research. NIH plays an essential role in training the next generation of endocrine researchers so that they may continue to explore new opportunities in this field. Talented young individuals need to be actively recruited into research careers in endocrinology and encouraged to continue these careers through the provision of stable and orderly periods of training. Only through sustained vigorous support for such training will a community of talented, well-trained, well-informed investigators be given the incentives required to encourage their interest in endocrinology research. With this goal in mind, the NICHD plans to develop research training programs to stem the loss of physician-scientists from the fields of reproductive and developmental endocrinology and to prepare a new type of scientist skilled in hormone chemistry as well as molecular biology.

Intramurally, the institutes of NIH cooperate particularly effectively in providing training to physicians embarking on research careers in endocrinology. Through the Inter-Institute Clinical Endocrinology Training Program, young physicians, coming to the NIH for research training in a particular laboratory that focuses on endocrine processes, receive training and experience in clinical endocrinology research from senior staff of one of the participating institutes. Trainees in the program routinely spend six full months and then one-half day per week during the remainder of their two- or three-year assignments at NIH, carrying out clinical research protocols and treating research subjects. Clinic assignments are divided between the NIADDK and the NICHD to ensure that trainees have ample exposure to the clinical endocrine conditions that are the focus of research at either institute. In addition, there is a formal structure of lectures, conferences and consultations with individual senior staff endocrinologists who make available to trainees the wide range of expertise in endocrinology available at the NIH.

Senior medical students from around the country also come to NIH for a highly popular three-month elective in endocrinology coordinated through the Inter-Institute Clinical Endocrinology Training Program. The students have no primary assignment to any one institute but rotate among the institutes to avail themselves of significant ongoing clinical research in endocrinology at the NIH. They participate in clinical protocols involving research in a large number of endocrine conditions and in a special lecture series designed to provide insight into normal endocrine physiology, endocrine disorders and current research approaches to these problems.

4. COORDINATION OF ENDOCRINE RESEARCH AT NIH

Endocrinology is a science that concerns itself with hormones--chemical agents that are secreted into the blood from ductless glands that act at distant target sites in the body to control important body functions. Because this area of investigation is intimately related to the more basic areas of biochemistry and cellular and molecular biology, progress in the clinical aspects of endocrinology, perhaps more than in any other field of medicine, is closely tied to advances in the basic biomedical sciences.

Hormones induce a vast array of biochemical effects in their target tissues that, in aggregate, influence all body tissues and organ systems. They regulate the growth of skeletal and soft tissue; strongly affect the maturation and function of the central nervous system; determine the physical and behavioral aspects of gender; and critically influence virtually every phase of the reproductive process. Hormones set the level of the basal energy requirement and are a major influence on the metabolism of sugars, fats, and proteins. They play a critical role in responses to environmental alterations (such as changes in temperature or the availability of food), to physical or chemical injury, and to infectious agents and immunologic challenges. Acting in concert with the nervous system, with which it is closely associated, the endocrine system integrates these responses in a manner most beneficial to the individual.

The field of endocrinology encompasses clinical disorders, such as, diabetes, thyroid diseases, and growth and reproductive disorders, that are among the most common in all of medicine and that have an enormous impact on human health and well-being and on the costs of medical care. Endocrine factors also play an important role in the causation, manifestation, and treatment of diseases that primarily are attributed to other organ systems and that are major causes of death and disability--diseases such as artherosclerosis, cardiovascular disorders, cancer, and psychiatric disorders. Not surprisingly, some form of endocrine research is supported by each of the institutes at NIH as well as several other organizational components. Also, because of the multifaceted nature of the field of endocrinology, resources required to support high quality research are at times beyond the capacity of any one institute and thus require cooperation and collaboration between two or more NIH components.

Research Programs

The research effort described in the previous sections are productive and cost effective because of the extensive cooperation and coordination that exists among the NIH institutes in their support of endocrine research. This includes: scientific collaboration between intramural scientists in different institutes, cooperative sponsorship of workshops and data banks, joint issuance of program announcements, transfer from one institute to another of pending research grant applications, and joint extramural funding by two or more institutes of research contracts and of research grants and interagency agreements.

Joint Exchanges of Information

The identification of promising areas for cooperative research undertakings and joint planning by staffs of the various institutes involved to assure adequacy of resources and program balance and to minimize unnecessary duplication of activity are examples of exchange of information.

For example, the NIEHS and the NIADDK have recognized as an area of special interest the interaction of the endocrine system with chemicals of environmental concern. With the special emphasis this problem will be receiving, significant progress in the understanding of toxic responses induced by chemical effects on the endocrine system is expected. As a result of the information obtained from this research, the NIEHS anticipates there will be greater need for clinical studies on the influence of environmental chemicals on the endocrine system. Such studies may produce a series of biologic markers that could be useful in the assessment and therapy of chemical injury to the endocrine system, as well as a better understanding of chemical toxicity in general.

Joint Solicitations of Research

Institutes with a common research interest may jointly issue: a Program Announcement of interest in a general field of research in order to elicit grant proposals; a Request for Applications for grant proposals on a specific research topic; and a Request for Proposals for research done by contract.

Program Announcements, Requests for Applications, and Requests for Proposals are published in the NIH Guide for Grants and Contracts, which is regularly received by thousands of biomedical research scientists and institutions. In addition, Requests for Proposals are also published in the Commerce Business Daily, which is received and scanned by private industries and educational institutions alike. An example of such a joint solicitation is the request by the NIADDK, the NIAID, and the NICHD for research grants on auto-immunity related to endocrine diseases.

Joint Assignment of Grant Applications

New grant applications to NIH are assigned to the most appropriate institute for funding. In the case where a grant application may overlap the research missions of two or more institutes, the relevant institutes may be assigned primary or secondary responsibility for the grant. This provides the opportunity for the grant to be considered by more than one institute for funding. The involved institutes may jointly fund the grant, or, in the case of budget limitations or extreme interest on the part of a specific institute, one or the other institute may fund the whole project.

In addition, program staff at different institutes with overlapping areas of interest are in close contact with each other. In the case of a meritorious pending grant application that may not be funded, program staff may bring the application to the attention of another institute which may provide funding.

Collaboration between Intramural Scientists from Different Institutes.

There is extensive sharing of information among intramural scientists from different institutes engaged in endocrinology-related research through informal contacts and scheduled or *ad hoc* seminars. These exchanges of information result in an extensive inter-institute collaboration in endocrinology-related research projects, and in turn, have resulted in a multitude of scientific publications with shared inter-Institute authorship.

Examples of such publications are:

> Rittmaster, R.S., Cutler, G.B., Sobel, D.O., Goldstein, D.S., Koppelman, M.C.S., Loriaux, D.L., and Chrousos, G.P. Morphine Inhibits the Pituitary-Adrenal Response to Ovine Corticotropin-Releasing Hormone in Normal Subjects. J. Clinical Endocrinology and Metabolism. 60:891-895, 1985. (NICHD, NHLBI, Nat. Naval Med. Ctr.)

Akatsuka, A., Singh, T.J., Nakabayashi, H., Lin, M.C., and Huang, K-P. Glucagon-Stimulated Phosphorylation of Rat Liver Glycogen Synthase in Isolated Hepatocytes. J. of Biological Chemistry. 260:3239-3242, 1985. (NICHD, NIADDK)

Reichman, M.E., Foster, C.M., Eisen, L.P., Eisen, H.J., Torain, B.F., and Simons, S.S. Limited Proteolysis of Covalently Labeled Gluco-corticoid Receptors as a Probe of Receptor Structure. Biochemistry. pp. 5376-5384, October, 1984. (NICHD, NIADDK)

Schulte, H.M., Chrousos, G.P., Gold, P.W., Booth, J.D., Oldfield, E.H., Cutler, G.B. and Loriaux, D.L. Continuous Administration of Synthetic Ovine Corticotropin-Releasing Factor in Man. J. of Clinical Investigation Inc. 75:1781-1785, 1985. (NICHD, NIMH, NINCDS)

Velletri, P.A., Aguilano, D.R., Bruckwick, E., Tsai-Morris, C.H., Dufau, M.L., and Lovenberg, W. Endocrinological Control and Cellular Localization of Rat Testicular Angiotensin-Converting Enzyme. Endocrinology. 116:2516-2522, 1985. (NHLBI, NICHD)

In addition to the large number of endocrine lectures and journal clubs sponsored by a single institute and attended by endocrine scientists in several institutes, an Inter-Institute Clinical Endocrinology Grand Rounds is held weekly at the NIH. All participating institutes share in selecting speakers for these lectures. Senior staff at NIH and leading endocrinologists from across the country speak on their latest research advances, many of which have relevance to aspects of endocrinology being pursued in other laboratories. This weekly conference, therefore, provides for the cross-fertilization of knowledge in endocrinology across institute boundaries.

Currently intramural scientists from the NIADDK and the NHLBI are collaborating in the investigation of the control of secretion of catecholamines with the use of medullary cells from bovine adrenal glands. In another collaborative effort between scientists in NCI and NHLBI laboratories, patients with malignant pheochromocytoma (a cancer that produces catecholamines) are being treated with experimental chemotherapeutic agents. Initial results indicate that partial remission can be produced in this disorder. Previously, there was no effective chemotherapy. Also, efforts are under way to determine the effectiveness of several new technologies in the diagnosis of hypertension thought to be caused by tumor-producing catecholamines.

In a collaborative effort between the NINCDS and the NIADDK, intramural scientists have developed Metaphit, a drug that blocks the action of the endopsychosin peptides and PCP. This drug may provide the first emergency room treatment for severe psychoses resulting from abuse of PCP. A collaborative project between NINCDS intramural scientists and researchers at Monsanto Company is investigating whether this research will lead to the development of a new class of antipsychotic drugs. High doses of PCP also produce an extremely effective anesthesia and analgesia. In a related collaborative project with the U.S. Army, an NINCDS investigator is attempting to develop a drug which will have the anesthetic effects of PCP without harmful side effects.

Research Resources

Similar coordination and cooperation is found when the various NIH components engage in collaboration to further endocrine research by providing needed research resources.

Joint Funding of Resource Contracts

A very important example of the cooperative provision of resources essential for endocrinology research, has been and continues to be the National Hormone and Pituitary Program, through which the NIADDK and the NICHD (and the Department of Agriculture) supply rare and unavailable hormones, anti-sera and similar substances to investigators in endocrinology.

Interagency Agreements

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, the National Heart, Lung, and Blood Institute, and the NIH Division of Research Resources cooperatively sponsor a contract with the National Diabetes Research Interchange by means of interagency agreements. Through this mechanism, human tissue samples are supplied to 160 researchers to facilitate meeting the requirements of 182 scientific protocols, many of which are endocrinology-related.

Conference Grants

Two or more Institutes frequently provide joint sponsorship for scientific conferences on selected topics in endocrinology. Examples of such conferences are:

- Gordon Research Conference on Mammalian Genital Tract (NICHD, NIADDK)

- Meeting on Growth Hormone Pituitary Cells in Molecular and

Cell Biology (NICHD, NIADDK)

- Gordon Research Conference on Hormone Action (NIADDK, NICHD, NIAID)

Resource Grants

At NIH, the Division of Research Resources is responsible for developing and ensuring the availability of multidisciplinary resources essential to the efficient and effective conduct of health research supported by the bureaus, institutes and divisions. The DRR fosters research coordination and collaboration between NIH-supported investigators who are the primary users of resources that include General Clinical Research Centers; Primate Research Centers; Laboratory Animal Sciences Grants; Minority Biomedical Research Grants; Shared Instrument Acquisition Grants; Biomedical Research Support Grants; and Biomedical Research Technology Resources.

An example of the indispensible endocrinology support provided by these resources is the trans-NIH provision of clinical beds through the General Clinical Research Center Program of the Division of Research Resources, which is not tied to the programs or funds of any single NIH Institute.

Coordinating Committees and Working Groups

Existing trans-NIH coordinating committees or interagency coordinating committees and other NIH working groups serve an important function in contributing to information exchange essential to planning and coordinating of cooperative undertakings related to endocrinology research. The NIADDK chairs an Interagency Committee concerned with the review of scientific questions surrounding the occurrence of CJD in recipients of pituitary-derived human growth hormone. Representatives from the Centers for Disease Control, the Food and Drug Administration, the NICHD and the NINCDS serve on this committee.

The Committee provides input and guidance on studies of infectivity of preparations of growth hormone administered to children, epidemiology studies of the population of recipients of pituitary-derived hGH, and studies to test the efficacy of purification methods to produce growth hormone preparations free from contamination.

Other committees and working groups include the Diabetes Mellitus Interagency Coordinating Committee, the NIH Nutrition Coordinating Committee, the NIH Coordinating Committee for Blood Related

Activities, the Inborn Errors of Metabolism Working Group, Inter-Institute Clinical Endocrinology Grand Rounds, and a variety of _ad hoc_ working groups.

5. CONCLUSIONS

Endocrinology represents one of the broadest areas of the biomedical research endeavor falling within the missions of the NIH bureaus, institutes, and divisions. Significant progress has been made in this field since the reports made to the Senate in 1979 and 1983. The recommendations of the 1979 report are being followed actively in terms of providing support for research and research training in endocrinology, as well as for resources essential to conducting such research. Many research advances in endocrinology have found clinical application, while others are providing the foundation for new directions in research which have vast promise for the future.

Selected developments and opportunities which hold hope for a further expansion in the base of knowledge in endocrinology have been described in this report. All available evidence suggests that NIH support for endocrine research has been critical to the advances achieved. This finding underscores the essential role NIH continues to play in supporting basic and clinical research in endocrinology and in training the next generation of researchers who will continue to explore new opportunities in this field.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH CARE FINANCING ADMINISTRATION

Report on the Baltimore, Maryland Facilities of the Health Care Financing Administration

March 1986

Report on the Baltimore, Maryland Facilities of the Health Care Financing Administration

This is submitted in response to a request contained in House of Representatives Report 99-289 from the Committee on Appropriations for a report on the adequacy of the facilities currently occupied by the Health Care Financing Administration (HCFA) in Baltimore, Maryland and on alternatives to these facilities which might be pursued by the Congress.

Since its creation in March 1977, HCFA has been housed in dispersed locations in the Baltimore metropolitan area. HCFA's headquarters currently utilize some 491,500 square feet of space in nine separate buildings in the Woodlawn section of Baltimore County. Approximately 169,000 square feet are in the Government-owned East High Rise and East Low Rise Buildings in Woodlawn, and 316,000 square feet are in seven leased buildings. Eight of these are office buildings and the ninth is a warehouse. HCFA shares approximately 5,800 square feet of joint use space in small blocks in five scattered buildings in the Woodlawn complex.

Many of the leased buildings lack ideal office space features and employee conveniences, i.e., food service, modern heating, ventilation and air conditioning systems, handicapped accessibility, security, credit union, employee activities association, access by public transportation, and health facilities. In addition, the dispersal of operational sites inhibits the operational efficiency of the organization as a whole.

In view of these recognized liabilities, in June 1980, the Secretary of this Department requested the assistance of the Administrator of the General Services Administration (GSA) in housing HCFA in a single site. Staff level discussions and planning ensued for several years. In 1985, we were advised by GSA that limited funds and the relatively low cost of rental space at the Woodlawn site led GSA to recommend that the status quo be maintained for at least 5 years.

In response to the Appropriations Committee's request, we have made a current review of the possibilities for housing HCFA and have considered five alternatives: building a new facility, relocating HCFA to existing Federal space, purchasing an existing facility not currently occupied by the Government, leasing such a facility, and maintaining the status quo. We enlisted the expertise of GSA in compiling the information required for our review.

GSA scrutinized the Federal space in the Baltimore metropolitan area and determined that there are no Government-owned buildings available for HCFA's use.

GSA also reviewed the real property currently available for purchase and found no buildings of sufficient size in the area that would satisfy HCFA's space requirements.

Three alternatives remain: Federal construction of a facility, leasing a single, large existing structure or maintaining the status quo.

If a long term lease of 491,500 square feet in a building to house HCFA in a consolidated location were entered into, the annual rental would be expected to be $11,058,750, fully serviced. The 30-year present value life-cycle cost of this alternative is $105,913,000.

The estimated cost to construct a 491,500 square foot Federal building to consolidate HCFA activities in the Baltimore area is $60,737,000 assuming that design were to begin in 1986. The new facility would include a full-service employee cafeteria, health unit, conference-training facilities, special files storage, microfilm storage, automated data processing areas, copy center, and mail conveyor system. The 30-year present value life-cycle cost of the alternative is $81,820,000.

If HCFA continues to be housed in its current locations, or in similar replacement space as current leases expire, the 30-year present value life-cycle cost of maintaining the status quo alternative is $77,194,000. This relatively low figure is possible because the Woodlawn leases are at or below current market rental rates, averaging $12.50 per occupiable square foot.

Cost analyses for FY 87 and for a 30-year life cycle for these three alternatives follow.

The firmest base for estimating the FY 87 costs of the status quo alternative is the FY 86 Standard Level User's Charge (SLUC) increased by an inflation factor for FY 87. GSA has determined that 7.5% will be the FY 87 inflation factor. When HCFA's FY 86 SLUC charge of $5,260,000 is increased by 7.5%, the resultant FY 87 SLUC charge is $5,655,000. HCFA will also require additional services costing $350,000 raising the total to $6,005,000.

The only FY 87 costs associated with constructing a new Federal building would be $75,000 for engineering and design work for the new structure.

If the lease option were pursued, the time required for acquiring the building and completing the extensive renovations which would be required would only call for the commitment of $75,000 for engineering and design work.

The costs for the two options above would be in addition to the SLUC charges which HCFA would continue to pay during FY 87 for its current housing.

Thirty-year life cycle cost estimates for the three options are outlined below:

30-Year Life Cycle

	STATUS QUO	LEASE	CONSTRUCTION
Data: Term used (years)	30	30	30
Occupancy	1986	1988	1990
Square footage in analysis	491,500	-	-
Leased	-	491,500	-
Government-owned	-	-	491,500

30-Year Life Cycle Continued

	STATUS QUO	LEASE	CONSTRUCTION
PRESENT VALUE COSTS (x$1000)			
Net rent	$38,449	$66,275	$ -
Construction cost	-	-	37,329
Land	-	-	568
Management, Design	-	-	4,056
Less: Building reversion	-	-	(4,708)
Land reversion	-	-	(132)
Interim housing	-	13,165	15,794
Major repairs and Tenant alterations	3,006	3,237	5,840
Maintenance	4,453	-	2,981
Service & Utilities	26,394	19,954	16,335
Property taxes, Insurance	3,537	2,572	2,369
Property Management	1,355	710	1,388
Total Present Value Cost	77,194	105,913	81,820
PROPOSAL VALUE			$-77,194
PRESENT VALUE COST ADVANTAGE			$ 4,626
OR			
EQUIV. ANNUAL COST ADVANTAGE			$ 373

FACTORS USED (Today's Values):
Net Rent (Status Quo): $10.20/osf
Net Rent (Lease): $18.00/osf
Operating Cost: $4.50/osf
Constr. Cost to Build New Bldg.: $82.00/gsf
Land Cost: $650,000
Discount Rate: 7%

The above data demonstrate that maintaining the status quo would afford a $4,626,000 30-year present value cost advantage over constructing a single site facility and a $28,719,000 30-year present value cost advantage over leasing a site.

Were the current contracts for leased space in Baltimore to be terminated early in order to move HCFA into a single site, the Government would incur significant termination costs. The leases for all seven leased buildings were negotiated within the last year. Each lease provides for Government termination earlier than the final expiration date, but the Government would still be required to pay significant rental costs even if early termination rights are exercised. The earliest termination date for each lease is indicated in the third column below:

Leased Building	Annual Rents	Earliest Termination	Final Expiration
Lyon	$501,397	08/31/89	08/31/94
Professional	$99,011	02/28/87	02/28/91
1705 & 1717 Equitable	$595,030	11/30/88	11/30/90
Meadows East	$1,102,077	05/25/89	05/25/90
Warehouse	$202,818	11/20/90	11/20/98
Oak Meadows	$458,105	10/28/87	10/28/91

It is clearly in the best interest of the Government to continue the status quo housing of HCFA. The benefit of the significant cost advantages outlined above will be obtained and substantial lease termination costs will be avoided.

HCFA has taken certain steps to ameliorate the inefficiencies inherent in the continuance of its dispersed operations. Word processors in each building, except the warehouse, are linked in a telecommunications network to avoid any unnecessary exchange of paper between facilities, and HCFA is experimenting with a state-of-the-art telephone messaging system. Its ability to send, receive and store messages in the caller's own voice shows great promise for reducing the need for staff to travel between buildings for face-to-face meetings.

To provide health care to employees in leased buildings lacking a health unit, HCFA has instituted a visiting nurse program in which health unit nurses make scheduled visits to these buildings.

In deference to the overriding interests of the Federal Government as a whole, this Department endorses maintaining the status quo housing of HCFA in Baltimore. As staffing changes occur in the future and program priorities shift, we will be vigilant for opportunities within this Agency to further consolidate HCFA and eventually achieve a single site which houses not only HCFA but also non-HCFA support groups, i.e., the Office of the Inspector General, the Office of General Counsel, and the General Accounting Office. We anticipate that housing these HCFA and non-HCFA personnel at a single site would require a total of 530,000 square feet.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

National Institute of Neurological and Communicative
Disorders and Stroke

Report on Hearing and Balance Disorders

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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REPORT ON HEARING AND BALANCE DISORDERS

INTRODUCTION

In its report on the Fiscal Year 1986 budget for the Department of Health and Human Services (DHHS), the Committee on Appropriations of the House of Representatives stated:

> "The committee requests, before next year's hearings, an overview of the scope and level of Federally-assisted research on hearing and balance disorders, encompassing research supported not only by the National Institutes of Health, but also by other Public Health Service agencies, the National Science Foundation, the National Aeronautics and Space Administration, the Veterans Administration and the Department of Defense." (House Report No. 99-289, page 54.)

The following report has been prepared by the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) of the National Institutes of Health (NIH) and coordinated with the Institutes and agencies involved in response to that request.

BACKGROUND

At present, it is estimated that there are 2 million deaf persons in this country and 15 to 20 million with lesser degrees of hearing impairment. Limited information is available on the prevalence and incidence of balance or vestibular disorders, but estimates indicate that in excess of 100,000 cases of Meniere's disease (a common balance disorder producing severe dizziness or vertigo) are diagnosed each year and that 42 percent of the adult population of the United States has complained of dizziness at some time.

FEDERALLY-ASSISTED RESEARCH ON HEARING AND BALANCE DISORDERS

The data analyzed for this report consist of the total obligations (including both direct and indirect costs) for Fiscal Years 1984 (actual) and 1985 (estimated) for each project supported by the National Institutes of Health; the Alcohol, Drug Abuse and Mental Health Administration; the Centers for Disease Control; the Health Resources and Services Administration; as well as the National Science Foundation and the Department of Defense. The National Aeronautics and Space Administration and the Veterans Administration were contacted for the requested information, but the data could not be retrieved easily in a form applicable to this report. This information will be submitted to the Committee when it is available.

The lead agency in both years was the NIH, accounting for over 83 percent of the support provided for hearing research. Each study is identified in Appendix A. The NINCDS is responsible for 73 percent of these studies which address a number of scientific issues that form the foundation for understanding the hearing mechanism and the diseases and disorders associated with it.

A number of NINCDS investigators are studying otitis media to improve the prevention, diagnosis and treatment of this common middle-ear disease found in infants and children. One recent finding, for example, showed that a medication commonly-used for treating otitis media was of no value. Other investigators are examining such disorders as noise-induced and drug-induced hearing loss, the degeneration of the hearing mechanism associated with the aging process, genetic disorders, as well as fluctuating and progressive hearing impairments.

Many answers to the problems presented by these diseases and disorders are sought by the basic neuroscientists who study both normal and abnormal conditions of the ear and the central nervous system. With NINCDS support, investigators use new techniques such as the electron microprobe and autoradiography to examine the development of normal and traumatized auditory systems. They explore the means by which sound is transmitted from the outer ears to the area of the brain responsible for receiving and interpreting the important sounds of speech and music. An example of the contribution of such studies to the treatment of persons with profound hearing losses may be found in the application of these findings to the design and use of cochlear implants (electrical stimulation of auditory neurons).

Funds from the other NIH components were expended in research for: treatment of otitis media; presbycusis (diminution of hearing associated with aging); the toxic effects of noise exposure and drugs; craniofacial anomalies and hearing loss; the genetics of hearing; and the relation between diabetes and hearing loss. This research has provided valuable information about the permanent damage caused by short, intermittent impulse noise on the hearing of individuals under such exposure, much in the same way that continuous, less intense noise has long been known to cause permanent damage to many workers in noisy work places. The other Federal agencies support research on echolocation, cerebral processing of auditory information, hearing protection against noise exposure, the relation between the use of alcohol and drugs and hearing loss, human response to military noise and psychotherapy for the deaf.

The majority of balance or vestibular studies are supported by the NIH, the National Science Foundation and the Department of Defense. The NIH accounts for about 83 percent of the support shown in Appendix B. The NINCDS proportion (65 percent) of the total funds expended supports a number of grants for basic studies of the normal development, structure and function of the balance mechanism. Studies of the impaired mechanism deal with procedures for preventing, diagnosing and treating such disabling disorders as dizziness and Meniere's disease. The results of this research have also been instrumental in the early detection and diagnosis of vestibular (balance) malfunction associated with ototoxic drugs that patients must take for the treatment of life-threatening infections.

The National Eye Institute contributes about one-eighth of the NIH dollars provided for the support of studies of balance disorders by funding a number of studies concerned with the oculomotor system. Three other Institutes provide funds for the study of balance disorders associated with the aging process, for maturation of the balance mechanism and for studies of motion sickness. Significant findings from these studies are sorting out the normal aging processes from abnormal degenerative sensory effects on postural control and are contributing to the management of falls so frequently experienced by the elderly. Funds provided by other agencies for research on balance disorders are concentrated in the areas of motion sickness, whole-body vibration and basic studies of vestibular system function.

SUMMARY

Table 1 summarizes the scope and level of Federally-assisted research on hearing and balance disorders. All agencies combined provided $42.9 million in Fiscal Year 1984 and $47.3 million in Fiscal Year 1985 for hearing research. The impact of this support is illustrated by the elucidation of mechanisms of auditory development that should permit early identification and treatment of the deaf child; by forming the basis for the pharmacological treatment of certain hearing disorders; and, by the development of a number of new techniques to increase our understanding of the hearing-impaired patient. The NIH's portion for those periods were $36.1 million and $39.3 million, repectively.

Four agencies provided $6.6 million for studies of balance disorders in Fiscal Year 1984 and $7.5 million in Fiscal Year 1985. The neural mechanisms of balance (equilibrium and orientation) are being clarified through the use of this support for the study of the function of neurons in the vestibular system. The understanding of this process has made a significant contribution to the design of tests of vestibular function, the management of patients with vertigo and the evaluation of hazards in space travel. Projects currently being funded and the supporting agencies are identified in Appendices A and B.

Table 1

FEDERALLY-ASSISTED RESEARCH ON HEARING AND BALANCE DISORDERS FY 1984 and FY 1985

Federal Agency*	Hearing		Balance	
	FY 1984	FY 1985	FY 1984	FY 1985
NIH				
NINCDS	$31,457,398	$34,333,159	$4,286,020	$4,862,489
NICHD	1,414,377	1,795,358	132,483	-120,905
NIA	722,938	522,191	229,529	237,799
NIAID	687,372	546,216		
NIEHS	233,227	523,541		
NIDR	181,988	192,590		
NIADDK	158,063	155,656		
DRR	952,417	1,088,819	174,738	173,569
NEI	93,761	85,073	960,353	742,807
NHLBI	80,258	0		
NIGMS	45,274	32,244		
NLM	47,088	0		
NIH Subtotal	**$36,074,161**	**$39,274,847**	**$5,7[illegible],123**	**$6,137,569**

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* Key to acronyms may be found at end of table.

Table 1
(Continued)

FEDERALLY-ASSISTED RESEARCH ON HEARING AND BALANCE DISORDERS FY 1984 and FY 1985

Federal Agency	Hearing		Balance	
	FY 1984	FY 1985	FY 1984	FY 1985
ADAMHA				
NIMH	$ 328,411	$ 409,399	$ 57,513	$ 60,467
NIAAA	274,705	221,793		
NIDA	108,909	134,132		
CDC				
NIOSH	440,831	108,034		
HRSA				
NCHSR	207,254	129,244		
NSF	2,220,966	2,028,255	257,104	345,771
NASA	(No data available)			
VA	(No data available)			
DOD				
Army	2,617,771	3,646,000		
Air Force	365,634	1,181,904		
Navy	275,000	117,000	535,000	915,000
Other Agency Subtotal	$6,839,481	$7,975,761	$849,617	$1,321,238
All Agencies Total	**$42,913,642**	**$47,250,608**	**$6,632,740**	**$7,458,807**

Table 1
(Continued)

Acronym	**Title**
NIH	National Institutes of Health
NINCDS	National Institute of Neurological and Communicative Disorders and Stroke
NICHD	National Institute of Child Health and Human Development
NIA	National Institute on Aging
NIAID	National Institute of Allergy and Infectious Diseases
NIEHS	National Institute of Environmental Health Sciences
NIDR	National Institute of Dental Research
NIADDK	National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases
DRR	Division of Research Resources
NEI	National Eye Institute
NHLBI	National Heart, Lung and Blood Institute
NIGMS	National Institute of General Medical Sciences
NLM	National Library of Medicine
ADAMHA	Alcohol, Drug Abuse, and Mental Health Administration
NIMH	National Institute of Mental Health
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIDA	National Institute on Drug Abuse
CDC	Centers for Disease Control
NIOSH	National Institute for Occupational Safety and Health
HRSA	Health Resources and Services Administration
NCHSR	National Center for Health Services Research
NSF	National Science Foundation
NASA	National Aeronautics and Space Administration
VA	Veterans Administration
DOD	Department of Defense

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FEDERALLY-ASSISTED RESEARCH ON HEARING AND BALANCE DISORDERS
FY 1984 and FY 1985

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APPENDIX A

FEDERALLY-ASSISTED RESEARCH ON HEARING DISORDERS FY 1984 AND FY 1985

NATIONAL INSTITUTES OF HEALTH

National Institute of Neurological and Communicative Disorders and Stroke (NINCDS)

Investigator/Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Neurophysiology of auditory hair cells and neurons	Syracuse University Syracuse, NY	$ 40,810	0
Binaural interaction in auditory evoked responses	University of Washington Seattle, WA	$ 41,827	0
Vocal-auditory interaction in echolocation	University of Missouri Columbia, MO	$ 39,286	0
Auditory analysis and sensorineural hearing loss	University of Minnesota Minneapolis, MN	$ 40,824	0
Effect of sound deprivation on the cochlear nucleus	University of Texas San Antonio, TX	$ 20,409	$ 58,320
Behavioral and neurophysiological hearing mechanisms	Loyola University Chicago, IL	$ 37,487	0
Bone resorption in chronic otitis media	University of Iowa Iowa City, IA	$ 43,397	$ 39,721
Aspects of inner ear immunology	University of California San Diego, CA	$ 44,548	$ 49,643
The neuroanatomy and physiology of the middle ear reflex	Massachusetts Eye and Ear Infirmary Boston, MA	$ 41,189	$ 42,202

(NINCDS, Continued)

Investigator/Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Perception of speech of hearing-impaired listeners	University of California Los Angeles, CA	$ 44,704	$ 62,417
Effect of furosemide on cochlear function	Southern Illinois University Springfield, IL	$ 40,160	0
Bilirubin toxicity in the developing auditory system	University of Wisconsin Madison, WI	$ 44,140	$ 57,586
Speech-recognition difficulties of the hearing impaired	Vanderbilt University Nashville, TN	$ 39,947	$ 52,638
Multineuronal interaction in auditory cortical columns	University of Pennsylvania Phildelphia, PA	$ 45,760	$ 50,080
Cell coupling in the inner ear	University of Medicine & Dentristry of New Jersey Newark, NJ	0	$ 54,432
CNS changes after cochlear damage	University of Virginia Charlottesville, VA	0	$ 64,400
Auditory profile analysis	Boston University Boston, MA	0	$ 57,680
Electrical development of cochlear hair cells	University of Colorado Denver, CO	0	$ 53,327
Response of inner ear to injury	Washington University St. Louis, MO	$162,636	$166,291
Histopathology of human temporal bones	Johns Hopkins University Baltimore, MD	0	$159,730
Adenoidectomy/tympanostomy tubes for otitis media	University of Texas San Antonio, TX	$349,584	$191,015

(NINCDS, Continued)

Investigator/Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Aminoglycoside ototoxicity--Gentamycin-carbenicillin complex	University of Chicago Chicago, IL	$125,781	0
Mechanical properties of the ear	Columbia University New York, NY	$230,678	$272,892
The nature of hearing	Princeton University Princeton, NJ	$139,123	$132,617
Auditory communication and its disorders	Central Institute for the Deaf St. Louis, MO	$970,009	0
Sensory processes	Syracuse University Syracuse, NY	$247,822	$267,820
Microscopic studies of the inner ear	University of Michigan Ann Arbor, MI	$ 38,384	0
Perception of complex auditory stimuli by the deaf	Gallaudet College Washington, DC	$154,127	$145,512
Mechanisms of sensorineural hearing loss	University of Michigan Ann Arbor, MI	$930,872	$986,403
Otopathology by light microscopy	Massachusetts Eye and Ear Infirmary Boston, MA	$180,447	$172,775
Metabolic processes of the inner ear	Washington University St. Louis, MO	$216,122	$239,143
Loudness summation, lateralization and fusion	Northeastern University Boston, MA	0	$ 69,991
Sensory cortex	Florida State University Tallahassee, FL	$124,689	$133,693

(NINCDS, Continued)

Investigator/Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Psychological studies of binaural hearing and attention	University of California Berkeley, CA	$100,427	$106,553
Embryology of the inner ear	Yeshiva University Bronx, NY	$350,178	$ 56,449
Studies in cochlear hair cell transduction	Northwestern University Evanston, IL	$232,180	$221,845
Otitis media with effusion	Ohio State University Columbus, OH	$322,969	$353,464
Encoding of vocal signals in the auditory system	Cornell University Ithaca, NY	$162,480	$251,644
Surpathreshold auditory behavior	University of California Los Angeles, CA	$124,622	$123,627
Communicative disorders clinical research center	University of California Los Angeles, CA	$560,394	$565,528
Development of cochlear prosthesis	Stanford University Stanford, CA	$299,914	$355,350
Binaural hearing	Massachusetts Institute of Technology Cambridge, MA	$197,550	$220,751
Neuro-otology clinical research center	Baylor College of Medicine Houston, TX	$449,308	$480,228
Lateral line pathways	University of Delaware Newark, DE	0	$ 76,934
Temporal factor in masking	Harvard University Cambridge, MA	$103,237	0

(NINCDS, Continued)

Investigator/Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Acoustic behavior--Its neural and developmental bases	Cornell University Ithaca, NY	$100,006	$109,598
Control of inner ear microcirculation	University of Michigan Ann Arbor, MI	$135,983	$146,029
Development of an acoustic prosthesis	University of California San Francisco, CA	$422,055	0
Innervational studies of auditory papillae	University of California San Francisco, CA	$112,574	$ 98,135
Auditory evoked brain potentials in neurological disease	University of California Irvine, CA	$332,842	$345,031
Phoneme confusions/reverberation/ age/hearing loss	University of Tennessee Knoxville, TN	$133,849	$196,062
Mechanics of the organ of Corti	Stanford University Stanford, CA	$106,201	$101,937
Stimulus encoding in the auditory system	Johns Hopkins University Baltimore, MD	$209,119	$288,231
Mechanisms of auditory and vestibular dysfunction	University of Minnesota Minneapolis, MN	$702,570	$745,518
Neural mechanisms for hearing	Duke University Durham, NC	0	$163,129
Morphology and physiology of the inner ear	University of California Berkeley, CA	$131,311	$138,267
Mechanisms of acoustic perception and orientation	University of North Carolina Chapel Hill, NC	$115,857	$122,399

(NINCDS, Continued)

Investigator/Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Internal organization of the dorsal cochlear nucleus	Johns Hopkins University Baltimore, MD	$122,359	$130,233
Research program on the neural basis of hearing	University of Wisconsin Madison, WI	$830,187	$848,276
Matching speech to residual auditory function	Massachusetts Institute of Technology Cambridge, MA	$347,757	$356,685
Behavioral analysis of the role of auditory cortex	University of Kansas Parsons, KS	$ 88,336	$120,831
Hearing aids and rehabilitation for hearing loss	University of California San Francisco, CA	$ 86,821	0
Basic and clinical studies of the auditory system	Massachusetts Eye and Ear Infirmary Boston, MA	$302,062	$802,993
Histopathology of temporal bones	Eye and Ear Hospital Pittsburgh, PA	$141,070	$153,723
Mechanisms of antibiotic induced hearing loss	University of Michigan Ann Arbor, MI	$163,738	$166,214
Tactile communication of speech	Massachusetts Institute of Technology Cambridge, MA	$197,668	$301,118
Anatomy of the auditory system	University of Connecticut Farmington, CT	$218,284	$216,449
Studies on neurogenesis	University of Connecticut Farmington, CT	$ 94,908	$136,710
Development of cerebral specialization	Salk Institute for Biological Studies San Diego, CA	$149,920	$167,256

(NINCDS, Continued)

Investigator/Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Middle ear response in serous otitis media	University of California San Diego, CA	$182,244	$210,788
Dynamic aspects of auditory synaptic terminals	University of California Los Angeles, CA	0	$220,935
Pathogenesis of otitis media	University of Minnesota Minneapolis, MN	$553,142	$566,954
Neurophysiology of sound localization	California Institute of Technology Pasadena, CA	$128,325	$187,697
Neuroanatomy of the auditory system	Duke University Durham, NC	$114,467	$142,810
Frequency analysis in normal and impaired listeners	Father Flanagan's Boys' Home Omaha, NB	$ 82,094	$ 87,110
Biochemistry of prominent auditory structures	University of Pennsylvania Philadelphia, PA	$127,327	$147,712
Studies of tonal interactions in the auditory system	Father Flanagan's Boys' Home Omaha, NB	$ 76,765	$ 31,875
Perception of binaural and complex sounds	Carnegie-Mellon University Pittsburgh, PA	$ 99,059	$ 79,700
Environmental influences upon auditory development	University of California San Diego, CA	$ 98,685	$170,128
Neuronal patterns and synapses in cultured cochlea	University of Wisconsin Madison, WI	$125,263	$141,030
Processing of acoustic information	Georgetown University Washington, DC	$154,916	$168,495

(NINCDS, Continued)

Investigator/Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Intracellular studies of the organ of Corti	University of Michigan Ann Arbor, MI	$135,025	$117,683
Afferent influences on nervous system development	University of Utah Salt Lake City, UT	$ 72,971	$ 97,304
Development and plasticity in the auditory system	New York University New York, NY	$ 65,910	$ 75,711
Mechanisms of auditory analysis by nervous systems	Loyola University Chicago, IL	$ 42,479	0
Afferent influences on auditory system ontogeny	University of Virginia Charlottesville, VA	$113,933	0
Auditory analysis and sensorineural hearing loss	University of Minnesota Minneapolis, MN	$174,861	$169,613
Speech perception by hearing-impaired listeners	Arizona State University Tempe, AZ	0	$ 95,855
Ontogeny of sensory processes	University of Virginia Charlottesville, VA	$185,142	$239,774
Coding in auditory neurons effects of amino acids	Southern Illinois University Springfield, IL	$ 51,958	$ 50,806
Electron microscopy of the human inner ear	Massachusetts Eye and Ear Infirmary Boston, MA	$ 61,853	$ 53,558
Intracellular study of cochlear nucleus	Stanford University Stanford, CA	$167,856	$178,069
Auditory adaptation for suprathreshold stimuli	University of Texas Austin, TX	$105,010	$166,565

(NINCDS, Continued)

Investigator/Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Hearing aid characteristic selection	Memphis State University Memphis, TN	$146,103	$119,843
Cochlear afferent transmitter search	Louisiana State University New Orleans, LA	$ 66,476	0
Analysis of space by the auditory system	Stanford University Stanford, CA	$180,561	$180,446
Identification of acoustico-lateralis transmitters	Wayne State University Detroit, MI	$ 81,422	$ 85,720
Auditory de-afferentation in the study of tinnitus	Yale University New Haven, CT	$ 97,490	0
Otitis media research center	Children's Hospital Pittsburgh, PA	$1,383,546	$ 54,785
Morphology and connections of the spiral ganglion	University of California San Francisco, CA	$120,079	$127,352
Auditory development-electrophysiological measures	University of Wisconsin Madison, WI	$164,817	$169,546
A study of electromechanical processes in the cochlear	Boston University Boston, MA	$151,078	$158,517
Acoustic trauma: hearing and single neuron activity	University of Texas Dallas, TX	$112,882	$115,995
The role of the stria vascularis in hearing dysfunctions	University of Minnesota Minneapolis, MN	$106,098	$101,096
Interaural time discrimination in noise	University of Connecticut Storrs, CT	$ 48,424	$ 43,901

(NINCDS, Continued)

Investigator/Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Structure of primary auditory cortex	University of California Berkeley, CA	$124,522	$1[illegible]8,256
Organization of the cerebral cortex	Boston University Bedford, MA	$110,706	$1[illegible]1,353
Structure and acquisition of American sign language	University of Illinois Champaign, IL	$161,457	$177,632
Discrimination of spectral shape by impaired listeners	Massachusetts Institute of Technology Cambridge, MA	$172,614	0
Complex sound processing	University of Akron Akron, OH	0	$ 68,916
Behavioral vs objective estimate of auditory function	University of California Los Angeles, CA	$ 91,350	$ 95,813
Behavioral contributions of dorsal cochlear nucleus	Florida State University Tallahassee, FL	$ 62,185	$ 74,017
Tinnitus in patients with sensorineural hearing loss	University of Maryland College Park, MD	0	$ 56,693
Microchemistry of the cochlear nucleus	Oral Roberts University Tulsa, OK	$ 87,524	$103,577
Organization of thalamocortical auditory system	University of Kansas Kansas City, KS	0	$134,860
Planar-curve analysis of auditory brain stem responses	University of California San Francisco, CA	$ 42,864	0
Development and regulation of axon terminal arbors	University of Utah Salt Lake City, UT	$155,929	$146,826

(NINCDS, Continued)

Investigator/Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Psychoacoustic studies of subjective tinnitus	University of Illinois Champaign, IL	$102,358	$ 75,546
Neural basis of complex-sound processing	Washington University St. Louis, MO	$193,296	$190,976
Electric response audiometry in infants and children	Children's Hospital San Diego, CA	$ 95,400	$104,456
A voltage-clamp study of cochlear responses	Boston University Boston, MA	$ 82,335	0
In vitro studies of the cochlear nucleus	University of Wisconsin Madison, WI	$ 54,393	$ 48,805
Brainstem binaural interactions--Function and structure	University of California Irvine, CA	$107,506	$160,623
Meniere's disease	Mayo Foundation Rochester, MN	$ 28,845	0
Rehabilitation strategies for the hearing impaired	City University of New York New York, NY	$494,761	$892,621
Auditory functions in the hearing-impaired	Northwestern University Evanston, IL	$ 50,185	0
Comparative study of sound localization	University of Kansas Parsons, KS	$ 51,914	$107,445
Morphometry of primary auditory cortex	University of Maryland Baltimore, MD	$ 49,590	$ 92,205
Pitch perception and auditory neural pattern theory	Michigan State University East Lansing, MI	$ 39,112	$ 66,188

(NINCDS, Continued)

Investigator/Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
High cholesterol diet and auditory dysfunction	University of Minnesota Minneapolis, MN	$ 70,576	0
Acquisition of literacy by deaf children and adults	Haskins Laboratories New Haven, CT	$ 62,585	$ 88,450
Hearing loss and perception of invariant acoustic cues	University of California Los Angeles, CA	$ 67,255	$ 76,098
Inferior colliculus neurons--Physiology and anatomy	University of Connecticut Farmington, CT	$ 94,693	$117,278
Printed circuit multichannel cochlear implant	University of Rochester Rochester, NY	$ 24,617	0
Intensity DIS and masking in normal and impaired hearing	Northeastern University Boston, MA	$ 87,971	$ 98,379
Single-neuron marking in the study of abnormal cochleas	Massachusetts Eye and Ear Infirmary Boston, MA	$139,558	$135,788
The parallel fiber system of the dorsal cochlear nucleus	Boston University Boston, MA	$ 68,512	0
Synaptic organization of auditory system	University of Connecticut Farmington, CT	$ 56,584	$109,318
Temporal mechanisms in acoustic processing	Loyola University Chicago, IL	$ 22,365	0
Auditory biophysics, neurobiology, and psychophysics	Washington University St. Louis, MO	$301,362	$217,729
Analysis of acoustical communication	Rutgers University New Brunswick, NJ	$ 58,712	0

(NINCDS, Continued)

Investigator/Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Auditory discrimination in handicapped children	Northwestern University Evanston, IL	$105,827	$107,089
Auditory gap detection in cochlear implant patients	Veterans Administration Los Angeles, CA	$ 2,300	0
Organization of auditory-motor pathways in the midbrain	Wake Forest University Winston-Salem, NC	$ 88,589	$ 72,175
Aspects of inner ear immunology	University of California San Diego, CA	$101,239	$ 46,850
Middle latency auditory evoked potentials	University of California Martinez, CA	$ 42,200	$ 39,092
Structure-function relations in middle ears	Massachusetts Institute of Technology Cambridge, MA	$ 67,258	$ 71,333
Encoding of complex stimuli in the auditory system	University of Washington Seattle, WA	$ 7,411	$ 92,888
Right hemisphere auditory pattern recognition	Cornell University New York, NY	$ 49,999	0
Noise induced reversible intracellular damage to the ear	Medical College of Georgia Augusta, GA	$ 55,675	0
Acoustic chiasm--Anatomy and behavior	Florida State University Tallahassee, FL	$ 94,160	$ 95,813
Proteins of the normal and pathological auditory nerve	University of Wisconsin Madison, WI	$ 75,527	0
The efferent auditory system and signal analysis	University of North Carolina Chapel Hill, NC	$ 46,278	$ 48,094

(NINCDS, Continued)

Investigator/Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Neurotransmitters in the auditory system	University of Connecticut Farmington, CT	$ 77,580	$ 73,659
Neural communication in hearing--Brainstem fiber study	University of Florida Gainesville, FL	$ 77,168	$ 71,808
Growth and regeneration in the inner ear	University of Hawaii Honolulu, HI	$ 71,374	$ 75,713
Auditory motion perception	Bill Wilkerson Hearing/Speech Center Nashville, TN	0	$ 71,022
Measurements of subjective and objective tinnitus	Purdue University West Lafayette, IN	$ 11,510	0
Identification of hair cell transmitters	Massachusetts Eye and Ear Infirmary Boston, MA	$141,439	$145,592
Electrophysiological correlates of speech signals	University of Washington Seattle, WA	$ 37,439	0
Central effects of peripheral hearing impairments	Lousiana State University New Orleans, LA	$ 89,408	$ 96,692
Neural mechanisms of binaural signal detection	University of Texas Dallas, TX	$ 80,868	$ 74,404
Physical and mathematical models of the pinna	Vibrasound Research Corporation Aurora, CO	$ 88,910	$109,903
Regional temporal bone bank centers	Massachusetts Eye and Ear Infirmary Boston, MA	$114,976	$121,519
Neuromagnetic and psychophysical study of tinnitus	New York University New York, NY	$119,564	$125,258

(NINCDS, Continued)

Investigator/Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Hearing loss and changes in central auditory processing	University of Texas Dallas, TX	0	$133,996
Response areas and spatial maps of auditory neurons	University of Illinois Chicago, IL	$ 68,807	$ 62,336
Using the MEG to clarify evoked sources in the brain	Massachusetts Institute of Technology Cambridge, MA	$ 61,135	0
Communication disorders in children	Father Flanagan's Boys' Home Omaha, NE	$355,970	$371,675
Effects of aging upon communication	University of Texas San Antonio, TX	$105,094	$105,295
Auditory areas in the cerebellum	University of Wisconsin Madison, WI	$ 81,496	0
Speech-language learning and early middle ear disease	University of Texas Dallas, TX	0	$240,515
Temporal processing of auditory signals in noise	University of California Los Angeles, CA	$147,607	$ 96,767
Clinical research center for communication disorders	Yeshiva University Bronx, NY	$384,250	$412,986
Studies in pediatric temporal bone pathology	University of Texas Dallas, TX	$100,568	$199,072
Mechanisms of bones resorption in chronic otitis media	Columbia University New York, NY	0	$212,396
Electrophysiologic evaluation of auditory cortex	New York State Department of Health Albany, NY	0	$105,545

(NINCDS, Continued)

Investigator/Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Language and cognitive flexibility in deaf children	University of North Carolina Greensboro, NC	$ 38,707	$ 33,613
Single cell marking studies of the auditory nerve	Harvard University Boston, MA	0	$216,913
Neuroanatomical development of the auditory system	Duke University Durham, NC	$ 51,083	$ 51,303
Spectral and temporal factors in binaural hearing	University of Illinois Champaign, IL	$103,914	$ 90,587
Olivocochlear efferent systems	Massachusetts Eye and Ear Infirmary Boston, MA	$132,015	$147,555
Neurobiology of asymmetries in brainstem potentials	Massachusetts General Hospital Boston, MA	$105,700	$108,451
Perceptual processing and memory of auditory stimuli	University of California Santa Cruz, CA	$ 72,782	$ 69,474
Experimental-theoretical studies of cochlear mechanisms	Massachusetts Institute of Techology Cambridge, MA	$178,648	$164,486
Skin vibrators for use with aids for the deaf	Audiological Engineering Corporation Somerville, MA	$227,647	$272,353
High-frequency acoustics in the external ear	Vibrasound Research Corp. Aurora, CO	0	$129,367
Transduction mechanism of hair cells	University of California San Francisco, CA	$136,237	$149,828

(NINCDS, Continued)

Investigator/Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Neonatal development of auditory frequency selectivity	University of Texas Houston, TX	0	$ 86,916
Cerebellar activity during sound stimulation and emission	University of Missouri Columbia, MO	0	$ 77,329
Discrimination and identification of auditory patterns	Indiana University Bloomington, IN	$ 89,591	$ 84,374
Study of auditory adaptation and masking	University of Texas Dallas, TX	0	$ 60,220
Mathematical modeling of cochlear mechanics	Father Flanagan's Boys' Home Omaha, NE	0	$ 48,531
Stimulus coding for scala tympani cochlear prostheses	University of Rochester Rochester, NY	$147,094	$154,823
Ontogeny of the spatial coding of sound frequency	University of Oklahoma Oklahoma City, OK	$ 77,991	$ 69,765
Postnatal development of auditory forebrain	University of South Carolina Columbia, SC	0	$ 45,317
Design moving platform for vestibular assessment	Neurometrix Portland, OR	$ 50,000	0
Computer automation of platform vestibular assessment	Neurometrix Portland, OR	$ 50,000	0
Signal processing hearing aid	Marshall Long/Acoustics, Inc. Santa Monica, CA	$ 50,000	0
Symposium - Central Auditory System	University of Illinois Chicago, IL	$ 15,532	0

(NINCDS, Continued)

Investigator/Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Statistical analyses of lateral superior olivary network	Rice University Houston, TX	$ 42,542	$ 45,028
Ultrastructure of connections of cortex	Boston University Bedford, MA	0	$108,334
Descending auditory pathways to cochlear nucleus	Athens, OH Ohio University	$ 37,107	$ 41,126
Statistical analyses of lateral superior olivary network	University of Texas Houston, TX	$ 75,881	$ 82,144
An advanced multi-channel cochlear implant for deafness	University of Melbourne Parkville, Victoria, Australia	$ 81,237	$104,578
Auditory and vestibular systems	Georgetown University Washington, DC	$ 58,238	$ 56,795
Mechanisms of tissue destruction in cholesteatoma	University of California, Davis Sacramento, CA	0	$158,046
MLR generator sites and course of development	Michael Reese Hospital & Medical Center Chicago, IL	$ 71,886	$ 53,665
Processing of complex auditory signals	Loyola University Chicago, IL	$ 67,665	0
Functional organization of the inferior colliculus	University of Texas Austin, TX	$112,282	$111,376
Sensory processing in a hair cell system	Loyola University Chicago, IL	0	$ 45,413

(NINCDS, Continued)

Investigator/Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Cytology and connections of the auditory system	Medical University of South Carolina Charleston, SC	$ 86,393	$ 83,650
Multimicrophone monaural aids for the hearing impaired	Massachusetts Institute of Technology Cambridge, MA	$223,086	$213,437
Commonalities in touch, hearing and vision	Pierce Foundation Laboratory New Haven, CT	$ 69,137	$ 73,707
Studies of the neural brainstem auditory responses	University of Pittsburgh Pittsburgh, PA	$105,251	$ 94,662
Cell-to-cell communication in the organ of corti	University of Medicine & Dentistry of New Jersey Newark, NJ	$124,819	$ 56,528
Development of artificial hearing for the deaf	Artificial Hearing System Corporation North Miami, FL	0	$ 50,000
Computerized written communication for the deaf	Emerson and Stern Associates Del Mar, CA	$ 50,000	0
Studies of the cochlear prosthesis	University of Michigan Ann Arbor, MI	$794,467	$745,169
Symposia for Association for Research in Otolaryngology	Albert Einstein College Bronx, NY	$ 31,442	$ 33,328
Electrical development of cochlear hair cells	University of Colorado Denver, CO	0	$ 85,084
Experimental cytomegaloviral labyrinthitis	University of California San Diego, CA	0	$150,561
Electrophysiological correlates of speech signals	University of Michigan Ann Arbor, MI	$ 93,469	$132,577

(NINCDS, Continued)

Investigator/Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Otosclerosis-like lesions	University of California Sacramento, CA	0	$135,556
Cochlear mechanics and neural encoding	Washington University St. Louis, MO	0	$199,745
Sensory hair cell proliferation in the ear	Georgetown University Washington, DC	0	$112,011
Neural elements underlying the ABR	University of Florida Gainesville, FL	0	$ 68,886
Parallel auditory pathways in the brain stem	Duke University Durham, NC	0	$113,695
Encoding of complex stimuli in the auditory system	University of Michigan Ann Arbor, MI	$ 86,315	$ 92,888
Pitch anomalies and the coding of pitch	University of Washington Seattle, WA	$ 67,558	$ 17,364
The organization of thalamo-cortical systems	Medical College of Georgia Augusta, GA	$ 23,135	0
Measurements of subjective and objective tinnitus	University of Washington Seattle, WA	$ 39,900	$ 55,255
Molecular mechanism of auditory transduction	Massachusetts General Hospital Boston, MA	$121,319	$ 78,956
Sound localization	University of Wisconsin Madison, WI	$190,911	$149,366
Cochlear emissions and psychoacoustic microstructures	Purdue University West Lafayette, IN	0	$ 78,100

(NINCDS, Continued)

Investigator/Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Development of frequency resolution in infancy	University of Virginia Charlottesville, VA	0	$ 73,152
Sensory mechanisms of hearing and vision	University of Pittsburgh Pittsburgh, PA	0	$ 35,419
Neural control of middle ear aeration	Mt. Sinai School of Medicine New York, NY	0	$225,940
Information processing by the auditory system	Loyola University Chicago, IL	0	$331,519
Iowa cochlear implant project	University of Iowa Iowa City, IA	0	$552,310
Neural mechanisms of sound localization	University of Connecticut Storrs, CT	0	$ 85,519
Dimensions of auditory perception	Brown University Providence, RI	0	$ 44,355
Mechanisms of tinnitus	Yale University New Haven, CT	0	$ 93,766
Binaural hearing before and after middle ear surgery	Northwestern University Chicago, IL	0	$ 64,443
Basic and applied studies of tactile perception	Central Institute for the Deaf St. Louis, MO	0	$ 93,782
Changes in auditory stereocilia during deafness	Medical College of Georgia Augusta, GA	0	$ 80,245
Cutaneous communication aids for the deaf	Johns Hopkins University Baltimore, MD	0	$128,633

(NINCDS, Continued)

Investigator/Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Voice-pitch tactile display for the deaf	Coulter Associates, Inc Vienna, VA	0	$ 49,746
Effects of organic acids on diuretic ototoxicity	Southern Illinois University Springfield, IL	0	$ 92,716
Ototoxic interaction: Loop diuretics and aminoglycoside	Oregon Health Sciences University Portland, OR	0	$109,800
Site and nature of hair-cell transduction	University of California San Francisco, CA	0	$ 47,968
Processor controlled hearing aid	Sam Cilman Associates Santa Monica, CA	0	$ 50,000
Signal processing high frequency audiometer	Audiometer Development Group Belmont, MA	0	$ 50,000
Electroacoustic device to assess high-frequency hearing impairment	Bolt Beranek and Newman, Inc. Cambridge, MA	$ 89,119	$ 22,548
Electrodes arrays based on thin film technology	Stanford University Stanford, CA	$243,852	$261,810
Scala tympani electrode arrays	University of California San Francisco, CA	$224,748	$249,148
Speech processors for auditory prostheses	Research Triangle Institute Research Triangle Park, NC	$207,029	$268,135
Speech processors for auditory prostheses	Stanford University Stanford, CA	$181,716	$220,102
Reading and writing skills in the congenitally deaf	Gallaudet College Washington, DC	$219,811	$258,094

(NINCDS, Continued)

Investigator/Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Mechanisms: a multidisciplinary analysis	Laboratory of Neuro-otolaryngology Bethesda, MD	$368,716	$385,677
Synaptic transmission in neuronal connection of the cochlear nucleus	Laboratory of Neuro-otolaryngology Bethesda, MD	$268,157	$280,492
Reading and writing skills in the congenitally deaf	Central Institute for the Deaf St. Louis, MO	$ 87,005	$232,807
Speech training devices for profoundly deaf children	Johns Hopkins University Baltimore, MD	$359,343	0
Central nervous system auditory prostheses study	University of Michigan Ann Arbor, MI	0	$264,107
Speech processors for auditory prostheses	University of Melbourne Melbourn, Australia	0	$ 62,454
	Total	**$31,457,398**	**$34,333,159**

National Institute of Child Health and Human Development (NICHD)

Investigator/Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Psychobiological aspects of auditory processes	University of Kansas Lawrence, KS	$ 31,829	$ 46,780
Respiratory illness and behavior	University of North Carolina Chapel Hill, NC	$ 31,829	$ 42,072

(NICHD, Continued)

Investigator/Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Structure and function of the central auditory system	University of Wisconsin-Madison Madison, WI	$ 20,567#	$ 28,322
Peripheral auditory system responses to speech sounds	University of Wisconsin-Madison Madison, WI	$ 20,567	$ 28,322
Clinical Neurophysiology	University of Wisconsin-Madison Madison, WI	$ 20,568	$ 28,322
Audiologic and speech-intelligibility studies	University of Wisconsin-Madison Madison, WI	$ 20,567	0
Auditory information processing	University of California Los Angeles, CA	$154,377	$178,419
Effects of tonsil-adenoid surgery on throat infection	Children's Hospital Pittsburgh, PA	$368,856	$479,551
Perception of speech and nonspeech sounds in infancy	Indiana University Bloomington, IN	$ 69,897	0
Perception of speech and nonspeech sounds in infancy	University of Rochester Rochester, NY	0	$ 53,983
The development of speech perception capacities	University of Oregon Eugene, OR	$ 80,578	$144,225
Neurobehavioral development in high risk-infants	National Jewish Hospital Denver, CO	$ 7,128	0

Projects occurring in sequence at the same location and with identical $ amounts represent applicable studies of a larger parent project.

(NICHD, Continued)

Investigator/Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Perception of rhythm and speech in infants	University of Texas Austin, TX	$112,081	$ 88,149
Auditory-visual perception of speech by infants	University of Washington Seattle, WA	$ 48,166	$ 45,310
Research on sound-making products for infants	BABECO Seattle, WA	$270,378	$218,191
BPIG for prevention of otitis media in infants	Case Western Reserve University Cleveland, OH	0	$170,878
Children with communication disorders	Yeshiva University New York, NY	$ 29,754	$ 38,215
Auditory research laboratory	Yeshiva University New York, NY	$ 29754	$ 38,215
Laboratory for auditory electrophysiology	Yeshiva University New York, NY	$ 29,755	0
Speech and hearing research program	University of Washington Seattle, WA	$ 67,726	$ 89,972
Auditory system integrity of high-risk infants	Yeshiva University New York, NY	0 -	$ 38,216
Behavioral and BER assessment of hearing in infants	Yeshiva University New York, NY	0	$ 38216
	Total	**$1,414,377**	**$1,795,358**

National Institute on Aging (NIA)

Investigator/Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Aging changes in cerebral cortex	Boston University Boston, MA	$ 88,356#	$ 4,058
Effects of age on auditory behavior	Boston University Boston, MA	$ 88,356#	$ 4,058
Anatomical changes in the lower auditory system	Boston University Boston, MA	$ 88,356#	$ 4,058
Aging and the auditory system	Northern Illinois University Dekalb, IL	$ 37,221	$ 48,816
Computer aided study of dendrites in aging brain	University of Rochester Rochester, NY	$ 81,814	$ 98,787
Experimental anatomical studies in presbycusis	Boston University Boston, MA	$107,386	$105,073
High resolution tactile aid for deaf and deaf/blind	Tacticon Corporation San Rafael, CA	$231,449	$ 69,589
Perception of natural and enhanced CV's	University of Maryland College Park, MD	0	$ 20,377
Aging - Cognitive/adaptive factors in auditory function	Baylor College of Medicine Houston, TX	0	$167,375
	Total	**$722,938**	**$522,191**

National Institue of Allergy and Infectious Diseases (NIAID)

Investigator/Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Viral infection in pneumococcal disease pathogenesis	University of Minnesota Minneapolis, MN	0	$118,177
Natural history and morbidity of otitis media	Boston City Hospital Boston, MA	$211,618	0
Preparation of bacterial polysaccharide immune globulin	Dana-Farber Cancer Institute Boston, MA	$158,536	$157,058
Immune mechanisms of middle ear disease	Children's Hospital Pittsburgh, PA	$ 88,395	0
Prophylaxis of H. influenzae and other infections	Johns Hopkins University Baltimore, MD	$228,823	$270,981
	Total	**$687,372**	**$546,216**

National Institue of Environmental Health Sciences (NIEHS)

Investigator/Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Ototoxicity of chemical asphyxiants and noise	Johns Hopkins University Baltimore, MD	$ 40,014	$ 53,568
Auditory effects of long exposures to low level noise	Medical University of South Carolina Charleston, SC	$112,607	$110,511
Ototoxicity of chemical asphyxiants and noise	Johns Hopkins University Baltimore, MD	$ 80,606	$ 75,269
The physiological bases of ototraumatic insult	Baylor College of Medicine Houston, TX	0	$159,227

(NIEHS, Continued)

Investigator/Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Interactions of drugs and noise exposure	University of Texas Austin, TX	0	$124,966
	Total	**$233,227**	**$523,541**

National Institute of Dental Research (NIDR)

Investigator/Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Model of cleft palate and ear disease	University of Pittsburgh Pittsburgh, PA	$ 46,655	$ 49,147
Otitis media and its consequences	University of Pittsburgh Pittsburgh, PA	$ 46,655	$ 49,147
Effect of palate repair on eustachian tube function	University of Pittsburgh Pittsburgh, PA	$ 46,655	$ 49,147
Cyclosporine in cranofacial composite tissue allografts	University of California Irvine, CA	$ 42,023	$ 45,149
	Total	**$181,988**	**$192,590**

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK)

Investigator/Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Genetic epidemiology of diabetes in rubella deafness	Virginia Commonwealth University Richmond, VA	$158,063	$155,656
	Total	**$158,063**	**$155,656**

Division of Research Resources (DRR)

Investigator/Title		**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Animal resources program	8 subprojects (FY 1984 and FY 1985)	$124,023	$199,941
Biomedical research support program	119 subprojects (FY 1984) 96 subprojects (FY 1985)	$290,166	$280,890
BRSG shared instrumentation program	13 subprojects (FY 1984) 14 subprojects (FY 1985)	$250,167	$318,786
Biomedical research technology program	10 subprojects (FY 1984) 7 subprojects (FY 1985)	$135,604	$ 38,964
General clinical research centers program	10 subprojects (FY 1984) 9 subprojects (FY 1985)	$125,686	$150,655
Minority biomedical research support program	1 subproject (FY 1984) 2 subprojects (FY 1985)	$ 26,771	$ 99,583
	Total	**$952,417**	**$1,088,819**

National Eye Institute (NEI)

Investigator/Title	Location		FY 1984 Award (actual)	FY 1985 Award (estimate)
Central nervous system control of eye movements	University of Wisconsin Madison, WI		$ 93,761	$ 85,073
		Total	$ 93,761	$ 85,073

National Heart, Lung and Blood Institute (NHLBI)

Investigator/Title	Location		FY 1984 Award (actual)	FY 1985 Award (estimate)
Isobaric inert gas counter diffusion on auditory and vestibular systems	University of Pennsylvania Philadelphia, PA		$ 80,258	0
		Total	$ 80,258	0

National Institute of General Medical Sciences (NIGMS)

Investigator/Title	Location		FY 1984 Award (actual)	FY 1985 Award (estimate)
Role of melanin in auditory form and function	University of Minnesota Minneapolis, MN		$ 45,274	$ 32,244
		Total	$ 45,274	$ 32,244

National Library of Medicine (NLM)

Investigator/Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Computer-based consultation system in deaf-blindness	University of Missouri Columbia, MO	$ 47,088	0
	Total	**$ 47,088**	**0**

National Institute of Mental Health (NIMH)

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Auditory competence and learning in infants	University of Massachusetts Amherst, MA	$ 53,590	$ 50,222
Behavioral analysis of sensory neocortex	Duke University Durham, NC	$ 43,414	$ 36,925
Comparative study of vocal learning	Rockefeller University New York, NY	$130,161	$122,400
Audition studies	New York State Psychiatric Institute New York, NY	$ 47,825	$ 46,619
Deafness and cognition dysfunction in the elderly	University of Washington Seattle, WA	$ 34,750	$ 35,750
Localization of sound in enclosed environments	Michigan State University East Lansing, MI	$ 18,671	0
Neuroethology of vocal learning	California Institute of Technology Pasadena, CA	0	$117,483
	Total	**$328,411**	**$409,399**

ALCOHOL, DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Fetal alcohol syndrome - Dose-response	University of Washington Seattle, WA	$132,168	$ 96,678
Alcoholism: family gender and CNS factors	University of Oklahoma Science Center Oklahoma City, OK	$142,537	$125,115
	Total	**$274,705**	**$221,793**

National Institute on Drug Abuse (NIDA)

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Drugs of abuse - Sensory psychophysical effects	Johns Hopkins University Baltimore, MD	$108,909	$134,132
	Total	**$108,909**	**$134,132**

CENTER FOR DISEASE CONTROL

National Institute for Occupational Safety and Health (NIOSH)

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Noise-induced hearing loss and high blood pressure	University of Pittsburgh Pittsburgh, PA	$ 32,400	0

(NIOSH, Continued)

Investigator/Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
The effects of impulse noise on the auditory system	University of Texas Dallas, TX	$120,635	0
Industrial noise - Potentiating interactions	University of Texas Dallas, TX	$ 91,776	0
Acoustic stapedius reflex and temporary threshold shift	University of Florida Gainesville, FL	$ 22,500	0
Hearing protection - Selection and communication issues	Virginia Polytechnic Institute Blacksburg, VA	$ 20,808	0
Noise control for honing machines	Hoover Keith and Bruce, Inc. Houston, TX	$ 43,431	0
Functional correlates of cochlear injury	Central Institute for the Deaf St. Louis, MO	$109,281	$108,034
	Total	**$440,831**	**$108,034**

HEALTH RESOURCES AND SERVICES ADMINISTRATION

National Center for Health Services Research

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Pediatrician education and maternal compliance	University of Rochester Rochester, NY	$207,254	$129,244
	Total	**$207,254**	**$129,244**

NATIONAL SCIENCE FOUNDATION

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Cytology and connections of auditory system	Medical University South Carolina Charleston, SC	$ 3,930	0
Multi-user equipment for hearing research	University of Texas Dallas, TX	0	$ 40,000
Cochlear afferent transmitter search	Louisiana State University New Orleans, LA	0	$ 63,211
Acquisition of a high-speed array processor	Massachusetts Institute of Technology Cambridge, MA	0	$ 61,700
Collaborative research on roll of anchors in perception	City University New York New York, NY	$ 50,000	0
Organization of auditory cortex	University of Wisconsin Madison, WI	$ 96,867	$103,987
Central auditory pathways	Duke University Durham, NC	$ 67,000	$ 72,000
Complex auditory processing	University of Massachusetts Amherst, MA	$ 53,215	$ 57,159
Combination of binaural interaction from different bands of frequency	Loyola University Chicago, IL	$ 38,843	$ 41,654
Sound pattern recognition and localization in noisy environments	University of Missouri Columbia, MO	0	$ 54,965
Analysis of models of auditory masking	Central Institute for the Deaf St. Louis, MO	0	$113,426
Quantitative models in psychophysics	Harvard University Cambridge, MA	$ 69,927	$ 77,019

(NSF, continued)

Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Serial acoustic pattern learning	Johns Hopkins University Baltimore, MD	$ 46,000	$ 51,500
Multi user equipment grant	Father Flanagan's Boys' Home Omaha, NB	$ 40,000	0
Multiuser equipment	Massachusetts Eye and Ear Infirmary Boston, MA	0	$ 70,000
Sound localizations	California Institute of Technology San Francisco, CA	$ 99,989	0
Sensory mechanisms	University of Pittsburgh Pittsburgh, PA	0	$ 40,062
Perception of complex auditory signals	University of Washington Seattle, WA	$ 68,126	$ 68,994
Additivity of auditory masking	University of Wisconsin Madison, WI	0	$ 51,578
Collaborative research on role of anchors in perception	City University of New York Brooklyn, NY	$ 50,000	0
Loudness perception and judgment	John B. Pierce Foundation New Haven, CT	$100,000	0
Perinatal auditory experience and behavioral inhibition	University of Connecticut Storrs, CT	$ 66,650	$ 36,466
International workshop on mechanics of hearing	Father Flanagan's Boys' Home Omaha, NB	0	$ 15,500

(NSF, continued)

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Mechanisms of sound communication	Cornell University Ithaca, NY	$ 41,331	0
Auditory processing of complex acoustic signals	University of Rochester Rochester, NY	$ 61,369	$ 65,261
Perception of motion in the auditory modality	California State University Los Angeles, CA	0	$ 79,000
Peripheral mechanisms of hearing	University of Minnesota Minneapolis, MN	$ 52,042	$ 55,093
Effects of noise on cochlear non-linearities	Medical University of South Carolina Charleston, SC	$ 52,948	$ 55,000
Processing of echoes	University of Oregon Portland, OR	$ 50,198	$ 46,000
Dynamic responses in the auditory nerve and cochlear nucleus	Syracuse University Syracuse, NY	$ 58,331	$ 74,500
Characteristics of hearing and its evolution	University of Michigan Ann Arbor, MI	$ 69,812	0
Experimental studies on isolated organ of Corti preparations	University of California Los Angeles, CA	$110,000	0
Proteins of the inner ear	Washington University St. Louis, MO	0	$ 82,823
Neuronal circuitry of the dorsal cochlear nucleus	Boston University Boston, MA	0	$126,783

(NSF, continued)

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Ascending and descending connections of the lower auditory system	Father Flanagan's Boys' Home Omaha, NB	$ 65,000	0
Perception of auditory temporal patterns	University of Wisconsin Milwaukee, WI	$ 42,500	$ 45,000
Psychophysical studies of suppression and forward masking	Father Flanagan's Boys' Home Omaha, NB	$ 53,452	$ 56,345
Multi user light microscope system	University of Wisconsin Madison, WI	$ 85,299	0
Morphology and connections of olivo-cochlear neurons	Creighton University Omaha, NB	$112,000	0
Morphological correlates of binaural auditory processing	University of Texas Austin, TX	$118,940	0
Tactile communication of speech	Massachusetts Institute of Technology Cambridge, MA	$112,000	$120,000
Neural mechanisms of sensory information processing	University of California San Diego, CA	$ 60,201	$ 69,000
Sensory transduction in microorganisms	Gordon Research Conference Kingston, RI	$ 17,000	0
Conference on sensory biology	Georgetown University Washington, DC	0	$ 10,000
Relationship between acoustic structure, signal message and receiver response	University of Wisconsin Madison, WI	0	$ 12,408
Individual recognition by voice communication systems	University of Washington Seattle, WA	$ 65,000	$ 52,821

(NSF, continued)

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Reflex modification of the acoustic startle reaction	University of Rochester Rochester, NY	$ 87,998	0
Somatostatin in the auditory system	Father Flanagan's Boys' Town Omaha, NB	$ 54,998	$ 59,000
	Total	$2,220,966	$2,028,255

DEPARTMENT OF DEFENSE

DEPARTMENT OF THE ARMY

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Noise reduction studies for combat vehicles	Human Engineering Laboratory Aberdeen Proving Ground, MD	$300,000*	$111,000*
Noise and blast effects	Human Engineering Laboratory Aberdeen Proving Ground, MD	$284,000*	$224,000*
Auditory performance of soldiers using AMC equipment	Human Engineering Laboratory Aberdeen Proving Ground, MD	$284,000*	$401,000*
Response of the ear to nonclassical pressure pulses	Ballistic Research Laboratory Aberdeen Proving Ground, MD	0	$ 51,000*
Auditory effects of blast overpressure	Aeromedical Research Laboratory Fort Rucker, AL	$484,000	$290,000
Hearing protection devices: Prevention of adverse physiological effects of noise	Aeromedical Research Laboratory Fort Rucker, AL	$347,000	$304,000

(Department of the Army, continued)

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Military acoustic hazards: Mechanisms of hearing loss	Aeromedical Research Laboratory Fort Rucker, AL	$338,000	$442,000
Evaluation of inner ears for loss of sensory cells	University of Texas Dallas, TX	0	$ 57,000
Effects of blast trauma on hearing	University of Texas Dallas, TX	$200,000	$210,000
Mathematical modeling of the hearing process	Rensselaer Polytechnic Institute Troy, NY	0	$ 72,000
Hearing protection	Sensor Electronics, Inc. Mount Laurel, NJ	0	$ 49,000
Support of ASA standards program	Acoustical Society of America New York, NY	$ 10,000	$ 10,000
Committee on hearing, bioacoustics and biomechanics	National Research Council Washington, DC	$ 25,000	$ 25,000
Direct determination of exposure limits for intense free-filed impulse noise	Los Alamos National Laboratories Los Alamos, NM	0	$1,400,000
	Total	**$2,617,771**	**$3,646,000**

DEPARTMENT OF THE AIR FORCE/OFFICE OF SCIENTIFIC RESEARCH

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Complex auditory signals	University of Florida Gainseville, FL	0	$163,184

(Department of the Air Force, continued)

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Auditory pattern recognition	Central Institute for the Deaf St. Louis, MO	$ 71,126	$ 83158
Dichotic listening to complex sounds	University of Arizona Tucson, AZ	0	$112,853
On categorizing sounds: context effects in tone identification	Duke University Durham, NC	0	$ 34,101
Levels of analysis of complex auditory stimuli	Yale University New Haven, CT	$ 84,171	$ 82,425
Auditory pattern memory	Purdue University West Lafayette, IN	$ 35,736	$ 41,629
Mechanisms mediating the perceptions of complex acoustic patterns	University of Wisconsin Milwaukee, WI	0	$ 93,806
Perception of complex auditory patterns	Indiana University Bloomington, IN	$112,100	$118,461
Binaural processing of complex stimuli	Loyola University Chicago, IL	$ 62,501	$40,288
DOD University Instrumentation Program	University of Wisconsin Madison, WI	0	$213,999
DOD University Instrumentation Program	University of Wisconsin Madison, WI	0	$198,000
	Total	$365,634	$1,181,904

DEPARTMENT OF THE NAVY

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Hearing conservation standard for hand-held underwater tools	Auditory Department, Naval Submarine Medical Research Laboratory Groton, CT	$154,000	$117,000
Development of pressure correction curves for audiometric earphones	Auditory Department, Naval Submarine Medical Research Laboratory	$121,000	0
	Total	$275,000	$117,000

APPENDIX B

FEDERALLY-ASSISTED RESEARCH ON BALANCE DISORDERS FY 1984 AND FY 1985

NATIONAL INSTITUTES OF HEALTH

National Institute of Neurological and Communicative Disorders and Stroke (NINCDS)

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Comparative neurophysiology	University of California La Jolla, CA	$ 43,538	$ 33,694
The oculomotor system and body postural mechanisms	Mount Sinai School of Medicine New York, NY	$131,600	$144,626
The cholinergic basis of central vestibular function	Columbia University New York, NY	$ 44,820	$ 59,184
Olivo-flocculo-vestibular system	Pennsylvania State University/ Hershey Medical Center Hershey, PA	$ 42,536	46,351
Clinical evaluation of the vestibuloccular reflex	Johns Hopkins University Baltimore, MD	0	$ 54,000
Vestibuloccular function in neurootological disorders	Eye and Ear Hospital of Pittsburgh Los Angeles, CA	0	$ 59,616
Otolith-optokinetic interactions	University of Minnesota/ Minneapolis-St. Paul Minneapolis, MN	0	$ 45,144
Physiology of vestibular system	University of Chicago Chicago, IL	$280,536	$261,895
Motor control	Rockefeller University New York, NY	$155,628	$167,596

(NINCDS, continued)

Title	**Location**	**FY 1984 Award** (actual)	**FY 1985 Award** (estimate)
Histopathology of the temporal bone	University of Chicago Chicago, IL	$125,781	0
Synaptology of vestibular nuclei	University of Chicago Chicago, IL	$125,781	0
Influences of the sacculus on posture and locomotion	University of Chicago Chicago, IL	$125,781	0
Electron microscopy of the inner ear	Massachusetts Eye and Ear Infirmary Boston, MA	$256,967	$211,859
Sensory mechanisms and motor control	University of Pisa Pisa, Italy	$ 22,000	$ 22,000
Experimental studies of vestibular mechanisms	University of California Los Angeles, CA	$224,590	$244,004
Clinical vestibular laboratory	University of California Los Angeles, CA	$186,798	$188,509
Vestibular physiology laboratory	University of California Los Angeles, CA	$186,798	$188,509
Vestibular studies	Baylor College of Medicine Houston, TX	$112,327	$120,057
Morphology laboratory	Baylor College of Medicine Houston, TX	$112,327	$120,057
Meniere's disease and the summating potential	Baylor College of Medicine Houston, TX	$112,327	$120,057

(NINCDS, continued)

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Peripheral and central contributions to vestibular reflex behavior	University of Minnesota Minneapolis, MN	$ 87,821	$ 93,190
Biophysical analysis of vestibular receptors	Eye and Ear Hospital Pittsburgh, PA	$ 77,555	0
Studies of control of posture	Good Samaritan Hospital and Medical Center Portland, OR	$115,946	$128,054
Neuronal organization of precerebellar and brainstem reticular nuclei	New York University New York, NY	$113,054	$166,933
Visual climbing and mossy fiber projections to the cerebellum	New York University New York, NY	$113,054	$166,933
Cerebellar vestibular system - Visual eye movement control	New York University New York, NY	$113,054	$166,933
Central mechanisms controlling gaze and head posture	University of Minnesota Minneapolis/St. Paul, MN	$112,359	$114,539
Muscular control of head movements	University of Illinois Chicago, IL	0	$ 80,021
Physiology of the vestibular system efferent neurons	University of Pittsburgh Pittsburgh, PA	$133,434	$132,974
Studies on vestibulospinal system	Rockefeller University New York, NY	$ 71,977	$171,461
A study of the role of aging on differentiation	George Washington University Washington, DCA	$ 78,630	$141,582

(NINCDS, continued)

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Neural projections of individual vestibular receptors	Mount Sinai School of Medicine New York, NY	$ 89,826	$ 89,989
Aminoglycoside induced vestibular ototoxicity	Good Samaritan Hospital and Medical Center Portland, OR	$ 60,580	$77,699
Control of postural sway trajectories	Good Samaritan Hospital and Medical Center Portland, OR	$129,779	$ 91,268
Central neural mechanisms of posture and stance	Good Samaritan Hospital and Medical Center Portland, OR	$169,499	$153,833
Cochlear and vestibular ion transport	Washington University St. Louis, MO	$ 87,213	$ 92,194
Olivo-flocculo-vestibular system	Pennsylvania State University/ Hershey Medical Center Hershey, PA	$ 54,060	$ 57,597
Adaptive changes in vestibular system	Rockefeller University New York, NY	$ 30,526	$ 32,086
Improved vestibular caloric test system	ICS Medical Corporation Addison, IL	$215,778	0
Moving platform vestibular assessment	Neurometrix Portland, OR	$ 50,000	$250,000
Computer automation of platform vestibular assessment	Neurometrix Portland, OR	$ 50,000	0

(NINCDS, continued)

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Parameter identification of postural control	Ohio State University Columbus, OH	0	$ 61,859
Brain stem sites and motor feedback in motion sickness	San Jose State College San Jose, CA	$ 41,740	$ 46,584
Vestibular responses to horizontal rotation	Eye and Ear Hospital of Pittsburgh Pittsburgh, PA	0	$ 57,280
Pharmacology of vestibular neurotransmission	Tulane University New Orleans, LA	0	$106,454
A model of endolymphatic hydrops	Baylor College of Medicine Houston, TX	0	$137,130
Differentiation and calcification of otoliths	Baylor College of Medicine Houston, TX	0	$ 86,138
Biophysical analysis of vestibular receptors	University of Southern California Los Angeles, CA	0	$ 72,600
	Total	$4,286,020	$4,862,489

National Institute of Child Health and Human Development (NICHD)

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Vestibular stimulation and retarded infant development	Vanderbilt University Nashville, TN	$132,483	$120,905
	Total	$132,483	$120,905

National Institute on Aging (NIA)

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Falls in the elderly	Albert Einstein College of Medicine Bronx, NY	$229,529	$159,560
Age-related changes in the vestibular labryinth	Florida Institute of Technology Melbourne, FL	0	$ 78,239
	Total	$229,529	$237,799

Division of Research Resources (DRR)

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Animal resources program	4 subprojects (FY 1984) 5 subprojects (FY 1985)	$156,640	$153,709
Biomedical research support program	5 subprojects (FY 1984) 6 subprojects (FY 1985)	$ 7,951	$ 11, 465
Biomedical research technology program	1 subproject (FY 1984) 1 subproject (FY 1985)	$ 10,147	$ 8,395
	Total	$174,738	$173,569

National Eye Institute (NEI)

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Visual control of the oculomotor system	Mt. Sinai School of Medicine New York, NY	0	$123,516

(NEI, Continued)

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Eye movement control	University of California Irvine, CA	$ 82,350	0
Analytic studies of visual perception	Pennsylvania State University University Park, PA	$ 24,996	0
Oculomotor system	Smith-Kettlewell Institute San Fransciso, CA	$133,082	0
Neural control of eye movement	University of California San Fransciso, CA	$114,824	$117,976
Properties of premotor neurons in gaze control system	Northwestern University Chicago, IL	$165,486	$168,046
Vestibular system activation during pitch while rotating	Brooklyn College Brooklyn, NY	$100,027	$104,804
Central and peripheral control of eye position	Good Samaritan Hospital and Medical Center Portland, OR	$147,927	$149,052
Role of cerebellar nodulus and uvula in gaze reflexes	Northwestern University Chicago, IL	$ 78,940	$ 62,630
Clinical evaluation of the vestibulo-ocular reflex	Johns Hopkins University Baltimore, MD	$112,721	$ 16,783
	Total	$960,353	$742,807

ALCOHOL, DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION

National Institute of Mental Health (NIMH)

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Vestibular and oculomotor functioning and psychopathology	Illinois State Psychiatric Institute Chicago, IL	$ 57,513	$ 60,467
	Total	$ 57,513	$ 60,467

NATIONAL SCIENCE FOUNDATION

Title	Location	FY 1984 Award (actual)	FY 1985 Award (estimate)
Structural and functional organization of Torus semicularis	University of Illinois Urbana, IL	$ 49,104	$ 52,769
Morphology and ultrastructure of vestibular nuclei	University of Texas Galveston, TX	0	$ 66,007
Central projections of the octavolateralis system	Georgetown University Washington, DC	$ 50,000	$ 55,000
Role of cerebellar noradrenergic system in the modification of vestibuloccular reflex	Temple University Philadelphia, PA	$ 70,000	$ 69,995
Octavolateralis systems and central sensory processing	University of California San Diego, CA	$ 88,000	0

(NSF, Continued)

Title	Location		FY 1984 Award (actual)	FY 1985 Award (estimate)
Comparative neurology of sensory processing: Octavolateral and related modalities	University of California San Diego, CA		0	$102,000
		Total	$257,104	$345,771

DEPARTMENT OF DEFENSE

Department of the Navy

Title	Location		FY 1984 Award (actual)	FY 1985 Award (estimate)
Perceptual responses induced by the vertifuge	Naval Aerospace Medical Research Laboratory Pensacola, FL		0	$ 25,000
Measurements of crew performance and motion sickness	Naval Biodynamics Laboratory New Orleans, LA		$209,000	$535,000
Seasickness reduction	Naval Biodynamics Laboratory New Orleans, LA		0	$ 43,000
Protection from seasickness and low frequency vibration	Naval Biodynamics Laboratory New Orleans, LA		$326,000	$312,000
		Total	$535,000	$915,000

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

National Heart, Lung, and Blood Institute

REPORT ON HYPERTENSION SPECIALIZED CENTERS OF RESEARCH AND THE FEASIBILITY OF THEIR EXPANSION

Thomas E. Malone, Ph.D.
Deputy Director, NIH

February 1986

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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REPORT ON HYPERTENSION SPECIALIZED CENTERS OF RESEARCH AND THE FEASIBILITY OF THEIR EXPANSION

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REPORT ON HYPERTENSION SPECIALIZED CENTERS OF RESEARCH AND THE FEASIBILITY OF THEIR EXPANSION

Executive Summary

In House Report No. 99-289, page 43, the Committee on Appropriations requested that the National Institutes of Health (NIH) provide the Committee with a special report on Hypertension Specialized Centers of Research (SCOR). The Committee further requested that the report include a discussion of the feasibility of expanding the Hypertension SCOR program and that the report be available to them in January 1986.

The NHLBI Specialized Centers of Research network was instituted approximately 15 years ago. It has been responsible for many of the clinical and basic science advances that have so benefitted the nation's health, and now provides a central focus for the national program on hypertension research. Because of the Hypertension SCOR program, the process of generating new, practical knowledge from basic science research and subsequent clinical investigations has been accelerated. The well-organized, highly efficient SCOR program can respond quickly to challenging new scientific questions and rapidly translate scientific advances into modern therapeutic strategies. The Hypertension SCOR program has clearly been a critical element in the NHLBI effort directed toward the understanding, control, and prevention of high blood pressure. Given the breadth of the existing research opportunities in hypertension and the number of qualified institutions that applied for the most recent renewal of the hypertension SCOR program, there are sufficient grounds to believe that an effective expansion of the present hypertension SCOR network is feasible. Expansion of the program would allow the SCOR network to play an even greater role in future NHLBI efforts and thereby hasten the arrival of further improvements in the management and prevention of a serious public health problem that presently afflicts almost 60 million Americans.

REPORT ON HYPERTENSION SPECIALIZED CENTERS OF RESEARCH AND THE FEASIBILITY OF THEIR EXPANSION

INTRODUCTION

In its report on the Fiscal Year 1986 budget for the Department of Health and Human Services, the House Committee on Appropriations stated:

> "Hypertension is one of the most prevalent of all cardiovascular diseases and a major risk factor for stroke. Almost 26 percent of the Nation's population, or 60 million persons, have hypertension. After years of intensive research into this problem it is generally accepted by the scientific community that hypertension is a problem in which a variety of factors play roles. The Institute, through its hypertension research centers program, which is multidisciplinary in nature, as well as through research grants and contracts and intramural research is pursuing many avenues of research with regard to hypertension including the role of neurobiological factors and elements in the diet such as sodium, calcium, potassium and amino acids. Advances in these areas may lead to more successful treatment of hypertension through diet and other nonpharmacological measures. More successful treatment of hypertension should result in a significant reduction in the overall incidence of cardiovascular disease and stroke, and therefore a significant reduction in health care expenditures for these diseases as well. The Committee requests the Institute to provide a special report on Hypertension Specialized Centers of Research in January 1986, including a discussion of the feasibility of expanding these centers." (House Report No. 99-289, page 43).

The following report has been prepared by the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health of the Department of Health and Human Services in response to this request.

BACKGROUND

The Specialized Center of Research (SCOR) was a new and promising idea when it was first announced by the then National Heart Institute (NHI) to the research community in 1970. It was judged by the Institute to be a potentially effective means of concentrating resources, facilities, and research personnel from several disciplines on selected high priority research topics in heart, lung, and blood diseases and resources. In the ensuing 15-year period an active and productive SCOR program has confirmed the accuracy of that judgment.

The Hypertension SCOR program began as part of the first NHI competition for SCORs announced in 1970, a competition that also included programs relevant to arteriosclerosis, pulmonary disease, and thrombosis. Each center was to be multi-disciplinary, including both a laboratory science and a clinical research emphasis, to ensure that advances ranging from basic sciences through clinical research could be rapidly implemented in the health care system. The Institute announcement indicated that the purpose of the centers was to expedite the development and application of new knowledge essential for improved diagnosis, treatment, and prevention of hypertension.

One year later, in 1971, five Hypertension SCORs were funded for a period of five years. As a result of competitive renewal of the program, four Hypertension SCORS were funded in the 1976-1980 period, five centers in the 1981-1985 period, and five will be supported for the next five years. The currently active Hypertension SCORs are located at the following institutions:

- Cornell University Medical College
- Vanderbilt University School of Medicine
- Boston University School of Medicine
- Harvard University (Brigham and Women's Hospital)
- Cleveland Clinic Research Foundation

Both the Cornell and Vanderbilt programs were in the originally funded group; Boston University joined the network in 1976, and Harvard and Cleveland Clinic were approved for funding in 1985.

The SCOR concept was expanded in 1984 so that individual applicants could compete for community-based demonstration and education components to enhance basic and clinical research programs and thereby become designated as National Research and Demonstration Centers (NRDCs). The expansion is viewed as an exciting new dimension. Boston University School of Medicine successfully competed as an NRDC and will perform demonstration and education research with the goal of improving the treatment of elderly hypertensives in a selected Boston community through heightening the effectiveness of medical and social supports. Such a program, uniting under one leader a scope of activities that extends from the laboratory bench to the public and health care community, is felt to be a promising way to encourage the translation of research advances into improved health.

ACCOMPLISHMENTS

The Hypertension SCORs have contributed to knowledge through the efforts of individual centers as well as through SCOR interaction and collaboration. Interaction is encouraged through the development of such individually coordinated projects, as treatment of hypertension using a common protocol, and through meetings such as the annual meeting of SCOR Directors and scientists.

Essential hypertension, the most prevalent form of hypertension, is complex and involves aberrations in a number of blood pressure control mechanisms, often in combination. As a consequence, the research approaches and the forms of therapy are many and varied. The following highlights are selected from the many significant contributions of the Hypertension SCOR Program during the 15 years since its inception.

- Dramatic advances have been made in drug therapy for hypertension. Before 1970 few drugs were available for controlling high blood pressure and these were associated with severe side effects.

Drugs developed since then have been more effective and better tolerated because their sites of action within the body have been better understood and targeted. One series of investigations included a study of the effectiveness of captopril, a recently developed drug that blocks formation of angiotensin II, a potent constrictor of blood vessels. The patients studied were unusual in that their hypertension was resistant to usual forms of drug treatment. Over a 2-year period, the drug proved remarkably effective in most of these cases, which also included renal failure, Raynaud's disease, and scleroderma. In addition, more recent studies of this drug have shown it to have an immediately beneficial effect on heart failure. It also inhibits cerebral arterial spasm in a canine model. The latter observation is of great significance for scientists interested in stroke.

Most recently, Hypertension SCOR scientists demonstrated a favorable effect of captopril in increasing renal and coronary blood flow, confirming observations that they made originally in animals. New uses for this drug, for example treating cerebral vessel and coronary vessel spasm with consequent improvement in blood flow to the brain and heart, respectively, are likely to prove beneficial in man.

- A recent observation is that changes in blood vessels due to hypertension resemble blood vessel changes due to aging. Specifically, in studies performed on laboratory animals it has been shown that age-induced histological changes in the vascular tree are often indistinguishable from changes induced by high blood pressure. Furthermore, these age-related changes are prevented in both normotensive and hypertensive rats when blood pressure levels are lowered with drugs. These observations suggest that blood pressure regulation, elevated blood pressure, and vascular aging are linked. How they are associated at the physiologic level is not known but the fact that they are linked is further evidence that some processes, formerly thought to be consequences of aging, may be modified or prevented. These observations led to further discussions which have resulted in a special program, jointly sponsored by the National Heart, Lung, and Blood Institute and the National Institute on Aging, seeking to clarify why blood pressure rises with age.

- A major advance in hypertension research over the past decade has been the recognition that the brain is critical in blood pressure regulation. Studies on the role of the central nervous system in cardiovascular control have benefitted from the application of techniques of contemporary neuroscience, as exemplified in the Hypertension SCOR program. An example is the application of new methods for mapping central pathways which have revealed connections between discrete brain centers for cardiovascular control located within the brain.

Important progress has also been made in identifying chemical messengers produced by neurons within the brain network. SCOR investigators have conducted research on a number of peptide hormones identified in the brain, such as vasopressin, cathecholamines, endorphins, and components of the renin-angiotensin system. They found that brain receptors for angiotensin II, catecholamines, and mineralocorticoids play key roles in blood pressure regulation in the rat. In a set of collaborations among Hypertension SCORs it was shown through the use of SKF 64139, an investigational neural blocking agent, that epinephrine (a catecholamine) in the central nervous system plays a major role in sustaining salt-dependent hypertension in the hypertensive rat model.

- Another significant contribution of SCOR-supported laboratories is the characterization of renin, a key enzyme involved in blood pressure control, and the development of an assay important for clinical diagnosis. It was also discovered during the past decade that 90 percent of circulating renin was in an inactive form, known as prorenin. A related discovery was that highly purified renal kallikrein is a potent activator of inactive renin and, in fact, it is the most potent known activator. In addition, it was found to be located uniquely on the intraluminal surface of the cells of the distal portion of the renal tubule. Thus, its location suggests that kallikrein may be an important activator of the renin-angiotensin system. This intriguing relationship between kallikrein and renin has already been confirmed by other laboratories, including another Hypertension SCOR group.

- Although the mechanisms through which sodium contributes to the elevation of arterial pressure are still only partially understood, it is widely believed that some human hypertension is the result of a high salt intake in genetically susceptible persons. A Hypertension SCOR Director recently published an extensive review of the role of sodium in hypertension. It describes salt sensitivity in great detail. Because this topic is often misunderstood and controversial, the review was especially timely.

- SCOR scientists are in the forefront of research on how dietary elements relate to the regulation of blood pressure. It has been accepted for many years that dietary sodium and potassium play a role even though the mechanisms are still a mystery. Now other dietary elements such as calcium, amino acids and proteins are being shown to have interesting effects. Administration of calcium supplements to hypertensive patients with low renin is associated with a favorable reduction in blood pressure. Research such as this and exploration of other non-drug therapies is especially important because the majority of patients with elevated blood pressure are only moderately or mildly hypertensive, and thus may potentially be treatable by means other than drugs.

- The Hypertension SCORs have provided leadership in the exciting area of research that is concerned with atrial natriuretic factor (ANF). This very interesting substance, recently identified in the heart wall (atrium), may play a role in blood pressure regulation. It promotes diuresis, relaxes blood vessels and lowers blood pressure. Although research in the field is moving rapidly, further studies are needed in order to determine more precisely which components of ANF are responsible for which of its properties, and ultimately what the function of ANF is in both health and disease. In the near future continued efforts by SCOR investigators should reveal to what extent ANF explains the regulation of blood pressure under normal circumstances, and what role it might be playing in the development of human essential hypertension.

- The clinical value of automatic 24-hour ambulatory blood pressure recording in a free-living environment such as the home or workplace has been assessed by one of the Hypertension SCORs. This advanced technology provides important information to help in deciding who among borderline hypertensive patients require therapeutic intervention.

- Preliminary evidence indicates that reduced calcium intake may be associated with the hypertension of pregnancy. The current controversy about the relation of calcium to primary hypertension stems, in part, from an inconsistency among results from different studies. This kind of scientific uncertainty often spurs the development of state-of-the-art studies within individual SCORs, exemplifying how they can respond to changing directions in a timely manner.

The present role of SCOR programs, including Hypertension SCORs, is very close to that perceived for them at their inception. SCOR programs provide a complement to the NHLBI portfolio of investigator-initiated grants. The centers have joined together basic and clinical researchers with many different areas of expertise in concentrated research efforts directed toward the discovery of underlying mechanisms of hypertension development that will lead to the development of potential improved methods for prevention and treatment. The preceding examples of advances attributable to Hypertension SCOR scientists attest to the productivity of these centers and to the care with which they are directed and managed.

FEASIBILITY OF EXPANDING HYPERTENSION SCORs

As recently as 1970 physicians were generally reluctant to treat moderate hypertension because of the cost, inconvenience, and side effects of drugs, and because there was little evidence of benefit. Although the Veterans Administration Cooperative Study had just established that treatment of moderate and severe hypertension reduced cardiovascular morbidity and mortality, the public was largely unaware of hypertension and the benefits of treatment. A majority of hypertensives had the condition without knowing it. Special problems of young and elderly and minority hypertensives were not appreciated.

Now, in the middle 1980's, the picture is more favorable. Blood pressure awareness is high, treatment is aggressive and effective, and mortality from stroke and heart disease is greatly diminished. These benefits have followed research successes that have produced better antihypertensive drugs (more effective, fewer side effects), improved ways of using these drugs, and enhanced public and professional awareness of the need to seek and retain a normal blood pressure level. Other important NHLBI programs, such as the National High Blood Pressure Education Program and the Hypertension Detection and Follow-up Program, have contributed greatly to this progress. Nevertheless, the ultimate research goal remains: to develop methods of prevention and nonpharmacologic treatment that can eliminate the need for the widespread use of pharmacologic agents.

That important advances have also been realized in basic hypertension research is clear from the above noted examples. Advances in treatment depend upon the results of basic science investigations. A survey of the current spectrum of hypertension research reveals an enormously active field with broad opportunities for creative exploration. Yet, despite the significant advances in methods of treatment and diagnosis and in clarifying the mechanisms underlying the development of hypertension, a great deal remains to be done. As part of a ten-year review and five-year plan of research in heart and vascular diseases conducted by the NHLBI in 1982, the Hypertension Task Group, comprised of highly respected scientists in the field of hypertension research, recommended the following:

> Further investigation of...mechanisms and interrelationships is of highest priority, including study of: the mechanisms of vascular smooth muscle reactivity and possible underlying defects associated with sustained contraction; role of genetic processes in both animals and humans; central and peripheral nervous system initiating events, pathways, transmitters, and actions; role of diet and excess bodyweight; role of humoral and hormonal systems; role of salt; and the interrelationships of these factors in the pathogenesis of hypertension.
>
> Development of new specific antihypertensive drugs and refinements in existing therapies should continue to be sought, including more practical approaches to the use of non-pharmacological treatment such as low salt, dieting, and weight loss. More effective regimens of antihypertensive therapy for special populations such as the elderly, the young, and blacks and other racial minorities should be established and the benefits and risks of such treatment determined. The groundwork should also be laid for more precise measures of the effectiveness of risk factor reduction in mild hypertension.

> Work should also be begun on development of improved scientific resources including new instrumentation, better animal models, and new biological material and reagents crucial to furthering biochemical and physiological understanding.
>
> Interdisciplinary research has been fostered through creation of Special Centers of Research, and through attracting new constituencies, such as microcirculation and neurobiology specialists, into the field. This approach should be continued and in the immediate future there is need to attract specialists in genetics and molecular biologists at all levels, from molecular processes to population dynamics.

The National Heart, Lung, and Blood Advisory Council (NHLBAC) in effect endorsed the Hypertension Task Group report and its recommendations; the NHLBAC relied extensively upon the Task Group Report in formulating its own recommendations on hypertension research for inclusion in the Tenth Report of the NHLBAC to the President and the Congress.

In recent years, research advances have led to increased emphasis on such areas as the control over blood pressure exercised by the central nervous system, the role of the microcirculation in hypertension, the applicability of molecular biological techniques to hypertension research, the relationship between nutrition and hypertension, and the development of hypertension-related cardiac hypertrophy. The present hypertension SCOR network of five centers is actively engaged in research in these and other critical areas of hypertension research.

The existence of the SCOR network provides an important central focus for the national program in hypertension research. Yet, when measured against the research needs and opportunities identified in the Hypertension Task Group Report, it is clear that the breadth of the Hypertension SCOR research program could be effectively expanded. The response from the research community to the most recent competition for hypertension SCORs made it apparent that the five current SCORs represent only a limited subset of the institutions capable of mounting strong SCOR programs. With their required mix of clinical and basic research and their multidisciplinary composition, SCORs are uniquely qualified to pursue the present research opportunities in hypertension with a clear focus on the likely clinical applications of the research results. The SCOR approach also assures at least a minimum coverage of the entire breadth of hypertension-related research. While the investigator-initiated activities continue to produce important research advances in hypertension, they tend to be oriented more toward basic science and concentrated more on a few selected areas that offer high research promise. Thus, the hypertension SCOR program provides an important complement to the hypertension-related research underwritten by other NHLBI support mechanisms.

There are a wide range of high priority hypertension research areas not currently addressed by the present SCOR program where the SCOR approach could be very productively applied. Among them are:

- Research on the basic mechanisms by which dietary nutrients influence blood pressure, combined with clinical studies which flow from the basic research. Hypotheses centering around modification of particular dietary nutrients to determine feasibility of preventing hypertension, or controlling it nonpharmacologically should be tested.

- Research on hypertension in the elderly. The elderly are an ever-expanding sector of the population subject to a variety of chronic diseases, including hypertension. Pathophysiological explanations for why blood pressure and the incidence of high blood pressure rise with age are lacking. Therapeutic approaches to the management of hypertension in the elderly are in need of improvement.

- Hypertension in the young. There is a need to determine which variables in children should be evaluated in order to predict who among normotensive children will become the adult hypertensives of tomorrow. Only then can interventions aimed at prevention of high blood pressure or nonpharmacologic control of blood pressure be fashioned.

- Hypertension in blacks and other minorities. As this chronic disease is more prevalent in blacks, as well as in other minorities (e.g., Japanese), laboratory and clinical comparative studies of hypertension in different minority groups should be conducted to shed new light on basic underlying mechanisms of blood pressure control, pathophysiological mechanisms responsible for the genesis of hypertension, and strategies for intervening in both therapeutic and preventive modes.

- Demonstration and education research. Recognizing that SCORs are potentially rich sources of demonstration and education research advances, the NHLBI offered to its SCORs the opportunity to compete for support as National Research and Demonstration Centers to integrate demonstration and education research activities with the SCOR laboratory and clinical components. Demonstration and education research investigates hypotheses related to health promotion and disease prevention in defined populations. The relationship between nutrition and hypertension and the incidence of hypertension in minorities, the elderly, and the young are all appropriate topics for demonstration and education research. Expansion of the Hypertension SCOR Program will also permit greater activity in demonstration and education research related to hypertension.

Given the scientific needs and opportunities in hypertension research and the known availability of qualified scientific expertise, an expansion of the Hypertension SCOR program would substantially accelerate progress against a disease now affecting over 25% of the nation's adult population.

CONCLUSIONS

Over the past 15 years, research advances in hypertension have produced significant improvements in the treatment of high blood pressure while also expanding substantially our understanding of the underlying mechanisms that contribute to the development of hypertension. Dramatic decreases in the morbidity and mortality associated with stroke and cardiovascular disease have occurred concurrently with the research advances.

The NHLBI Specialized Centers of Research network was instituted approximately 15 years ago. It has been responsible for many of the clinical and basic science advances that have so benefitted the nation's health, and now provides a central focus for the national program on hypertension research. Because of the Hypertension SCOR program, the process of generating new, practical knowledge from basic science research and subsequent clinical investigations has been accelerated. The well-organized, highly efficient SCOR program can respond quickly to challenging new scientific questions and rapidly translate scientific advances into modern therapeutic strategies. The Hypertension SCOR program has clearly been a critical element in the NHLBI effort directed toward the understanding, control, and prevention of high blood pressure. Given the breadth of the existing research opportunities in hypertension and the number of qualified institutions that applied for the most recent renewal of the hypertension SCOR program, there are sufficient grounds to believe that an effective expansion of the present hypertension SCOR network is feasible. Expansion of the program would allow the SCOR network to play an even greater role in future NHLBI efforts and thereby hasten the arrival of further improvements in the management and prevention of a serious public health problem that presently afflicts almost 60 million Americans.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

REPORT ON IMMUNOLOGY RESEARCH

Thomas E. Malone

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Deputy Director, NIH

February 1986

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

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REPORT ON IMMUNOLOGY RESEARCH

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REPORT ON IMMUNOLOGY RESEARCH

Executive Summary

In House Report No. 99-289, the Committee on Appropriations requested that NIH prepare a report on immunology research (p. 37). The following is submitted in response to that request.

In February 1984, the NIH submitted a report to the Committee on Appropriations on immunology research. That report described in detail the relevance of immunology to each of the NIH institutes, and to many diseases under study. It stated the priorities of each of the NIH institutes for immunology research.

Since the 1984 report, significant progress has been made in carrying forward the research priorities discussed there. This report presents priorities, progress and current and planned activities in immunology research of: the National Institute of Allergy and Infectious Diseases; the National Cancer Institute; the National Heart, Lung, and Blood Institute; the National Institute of Dental Research; the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases; the National Institute of Neurological and Communicative Disorders and Stroke; the National Institute of General Medical Sciences; the National Institute of Child Health and Human Development; the National Eye Institute; the National Institute of Environmental Health Sciences; the National Institute on Aging; and the Division of Research Resources.

In addition this report describes activities of agencies not covered in the earlier report, namely: the Centers for Disease Control; the Food and Drug Administration; the Alcohol, Drug Abuse, and Mental Health Administration; the Health Resources and Services Administration; and the Veterans Administration.

The following statement from the 1984 report remains true: "Immunology is one of the broadest areas of research supported by NIH, with relevance to many diseases and to every one of the NIH Institutes. There has been an explosive growth of immunology research. All NIH funding mechanisms are used to support this work. The greatest number of studies are supported through investigator-initiated research project grants, which generally deal with basic immunology research. The institutes build on the fundamental knowledge generated by research project grants through other support mechanisms, such as research contracts and center grants, in projects directed at the diagnosis, prevention, and treatment of many specific diseases."

There was a separate section in the 1984 report concerning coordination of immunology research programs, where it was noted that: "Extensive cooperation and coordination exists among the NIH institutes in their support of immunology research. This includes scientific collaboration between intramural scientists in different institutes, cooperative sponsorship of workshops and data banks, joint solicitation of immunology research projects, transfer from one institute to another of pending research grant applications, joint extramural funding by two or more institutes of research contracts and conference grants, and extensive sharing of research reagents and results." This coordination and collaboration remains vigorous. Examples of current or planned collaborative activities, especially with regard to clinical application, are given in this report.

Past and projected funding by each NIH institute for immunology research is presented.

REPORT ON IMMUNOLOGY RESEARCH

INTRODUCTION

In its report on the Fiscal Year 1986 budget for the Department of Health and Human Services, the Committee on Appropriations stated:

> "The Committee wishes to encourage further research on the diagnosis, treatment and prevention of immune-system-related diseases. In an earlier report to this Committee, the National Institutes of Health indicated its continuing commitment to immunology research, including collaborative activities. The NIH has established a list of research priorities for each institute. The Committee believes it is important to carry forward these priorities and accelerate the application of immunologic research to direct patient care and disease prevention. With this in mind, the Committee requests an update with regard to (a) the progress made by NIH in carrying forward the research priorities reflected in the earlier report, (b) scope of research activities into immune-related disease conducted by other Public Health Service agencies and the Veterans Administration, and (c) identification of current or planned collaborative activities, especially with regard to clinical application. The progress report should include an update of funding patterns supporting basic and clinical immunology." (House Report No. 99-289, page 37)

The following report has been prepared by the National Institutes of Health of the Department of Health and Human Services in response to this request. Information on "current or planned collaborative activities, especially with regard to clinical application" appears in this report within the discussion of the activities of the individual Institutes, rather than as a separate section.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

The NIAID devotes approximately 40 percent of its total extramural research budget to the Immunology, Allergic and Immunologic Diseases Program (IAIDP), which manages approximately 700 grants. Most of these are individual research project grants; however, the IAIDP also supports: 21 multidisciplinary Program Project awards for studies of the biology of the immune system, mechanisms of immunologic diseases, and transplantation immunology; 13 Asthma and Allergic Diseases Centers; and 5 Centers for Interdisciplinary Research on Immunologic Diseases.

The remaining 60 percent of NIAID's extramural research budget is devoted to the Microbiology and Infectious Diseases Program (MIDP). The MIDP has a major program for the development of vaccines, which use the immune system to prevent infectious diseases. Under active development are vaccines for influenza, whooping cough, hepatitis, gonorrhea, genital herpes, malaria, and many other diseases.

Approximately 35 percent of the NIAID's Intramural Research Program budget is allotted for support of immunology in four laboratories and several sections of other laboratories. In addition to research on the immune system as an organ system, studies include those on asthma, allergies, immune deficiency diseases, organ transplant rejection, and immunologic responses to infections by microorganisms.

NIAID has a major research program on acquired immunodeficiency syndrome (AIDS). The effects of AIDS on the immune system are being intensively studied, and collaborative clinical trials are under way that are attempting to enhance immune function in AIDS patients.

Immunobiology and immunochemistry research is concerned with the basic biology and chemistry of the immune system. Areas of emphasis include studies on the origin, maturation, and function of immunologically active cells and on the mechanisms involved in the regulation of immune reactivity. Increased capability to clone individual immunocompetent cells, particularly specific subpopulations of T lymphocytes, is permitting detailed studies of the molecular structure and functions of their surface molecules involved in the recognition of foreign components and the subsequent activation of the immune system. The recent identification and isolation of the T cell receptor and the cloning of the genes responsible for its synthesis represent major accomplishments that provide the opportunity to clarify molecular mechanisms controlling the immune system.

Genetics and transplantation biology research is concerned with the effects of genes and gene products on the immune system, organ transplantation phenomena, and genetic determinants of disease resistance and susceptibility. Among the techniques being emphasized are strategies to minimize graft rejection by improved immunosuppressive regimens. Hybridoma technology is being exploited for diagnostic and therapeutic purposes; a large number of monoclonal antibodies are now available for rapid and precise identification of microbial infections and disordered immune function. Coupling various toxins to monoclonal antibodies has provided an approach for specific immunotherapy and regulation of immune function. To facilitate this effort, the NIAID contractually supports, together with other NIH institutes, a computerized registry of hybridoma data and makes this information as well as hybridoma cell lines available to the research community. Collaborative clinical trials of monoclonal antibodies in kidney and bone marrow transplantation are under way. Because bone marrow transplantation is used to reconstitute the immune system when it has been compromised by hematological malignancy or inherited or acquired immunodeficiency, means to ensure successful retention of marrow transplants without untoward effects is of great importance.

Asthma and allergic diseases research is concerned with developing improved methods of diagnosis, prevention, and treatment. Areas of emphasis include investigations on factors that contribute to asthma, such as allergens and infections; immediate-type hypersensitivity and its disorders (allergic rhinitis, atopic dermatitis, urticaria, and angioedema); and immunoglobulins, particularly IgE. Studies have begun on the effects of Omega-3 fatty acids, which are present in fish oil diets and have anti-inflammatory actions, in the prevention and treatment of asthma and allergic inflammatory disorders. Marked expansion of knowledge concerning the chemical mediators of inflammation is providing important new therapeutic approaches. Recent information on the leukotrienes is offering promise for the development of pharmacologic agents that may be useful in the management of asthma and other allergic disorders. NIAID recently began a five-year collaborative multicenter study of injection treatments in adult asthmatics allergic to either ragweed or house dust. Also under way is a clinical trial of the efficacy of injection treatments for those at risk of allergic reactions to animal pets or through occupational exposures.

Clinical immunology and immunopathology research is concerned with the prevention and management of immunologic disorders. Studies of systemic lupus erythematosus have demonstrated that a specific form of autoantibody may be responsible for the production of kidney manifestations. Efforts have increased to understand immunoregulatory mechanisms, including the structure and function of naturally occurring substances, such as interleukins, and to develop the capability to control undesired immune responses with various drugs, such as cyclosporine.

The effects of certain food additives, air pollutants and commonly used pharmaceuticals in the production of severe asthma and life-threatening anaphylactic shock reactions are being identified and reported with increasing frequency. Certain volatile chemical agents prevalent in industrial settings are also being increasingly recognized as causes of occupationally incurred asthma and immunologic lung diseases. Therefore, NIAID is placing increased emphasis upon collaborative investigations to identify those at risk both among general population groups and at work sites and to develop improved measures for the diagnosis, treatment and prevention of these disorders.

The recent discovery of an interaction between the immune, endocrine and nervous systems has potential importance in many clinical settings. As part of studies to understand these interactions, NIAID scientists have demonstrated that two neuropeptides (adrenocorticotropic hormone and beta endorphin) increased the proliferation of activated B cells. Future studies will characterize the nature of the interaction of these neuropeptides with human B cells and help clarify the potentially very important interactions of the immune-endocrine-neurologic networks.

NATIONAL CANCER INSTITUTE (NCI)

The NCI is continuing basic research to study the efficacy of various immune mechanisms in preventing or controlling the growth of tumor cells. Transfer of basic research findings to clinical applications is being fostered through effective collaboration of basic and clinical researchers. It is becoming apparent that different types of tumors vary in their susceptibility to killing by specific types of immune cells. The basis for this differential resistance to immune control is still unclear, and may be due to differences in the composition of the surface membrane of the tumor cell. Research is continuing to develop procedures to increase the effectiveness of the immune system by enhancing the killing capacity of immune cells or by increasing the susceptibility of tumor cells.

Genetic engineering and other molecular biology techniques are making available large sources of purified soluble factors that modulate the immune system. Several of these factors, such as the interferons and interleukin-2 (IL-2), are being tested clinically for their anti-tumor effect in cancer patients. In addition, purified factors are enabling the growth in cell culture of large numbers of immune cells with anti-tumor activity. These cells, when transferred into an animal or patient, can mediate an anti-tumor immune response. Promising initial results have been obtained by treating cancer patients with lymphokine-activated killer (LAK) cells -- lymphocytes taken from the patient, activated in culture with IL-2, and returned to the patient. An ongoing clinical trial of this treatment has yielded encouraging patient responses. Other immune cell types being studied include natural killer cells (augmented with interferon), cytotoxic T lymphocytes (enhanced with IL-2), and monocytes/macrophages (armed with monoclonal antibodies or activated with macrophage activating factor, which has properties similar to gamma-interferon).

Candidate immune modulators, also referred to as "biological response modifiers," are being screened for anti-tumor activity in model systems to provide a rational basis for selection of agents to be considered for further clinical evaluation. To expedite bringing monoclonal antibodies to clinical trials, researchers are focusing on preparation of conjugates of monoclonal antibodies with drugs, toxins, and radionuclides, and on developing rapid screening methods to evaluate efficacy in cell culture and animal model systems. Several collaborative clinical studies are under way to evaluate these antibodies, either alone or as conjugates, for the detection or treatment of melanoma, leukemias/lymphomas, colon, breast and lung carcinomas. These monoclonal antibodies are leading to improved diagnosis and classification of tumors, and may have potential for detecting early recurrence of tumors after surgery or radiotherapy. Clinical studies are commencing to evaluate the effectiveness of intralymphatic administration of monoclonal antibodies for improved antibody delivery to sites of tumor metastases.

Monoclonal antibodies are being developed to further analyze the temporal development of specific immune defects in AIDS, to monitor closely the distinct steps in the progression of this disease, and to determine the potential to reverse the course of the disease at various stages. The factors leading to development of Kaposi's sarcoma in some but not all AIDS patients, and the cell of origin of this malignancy, are being investigated. In addition, an intense collaborative research effort is under way to develop a vaccine against HTLV-III, the retrovirus identified as the cause of AIDS.

Monoclonal antibodies are being used successfully to eliminate the immune cells responsible for the occurrence of lethal graft-versus-host disease which often follows bone marrow transplantation, making this an effective curative treatment for various leukemias and lymphomas. Monoclonal antibodies are also being used to eliminate any tumor cells that may have metastasized to the patient's bone marrow, thus allowing for the use of the patient's own bone marrow for transplantation to rescue the immune system following very high doses of effective, but toxic, chemotherapy or radiotherapy.

To study the role of genetics in controlling the immune response and susceptibility to cancer, scientists have initiated studies to evaluate the relationship of natural immunity to the increased incidence of cancer in certain ethnic populations.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)

The NHLBI supports immunology research in each of its programmatic areas. Included are studies of atherosclerosis, hypertension, coronary heart disease, rheumatic heart disease, heart transplantation, and myocarditis; pulmonary fibrosis, acute respiratory failure, asthma, granulomatous inflammatory diseases including sarcoidosis, farmer's lung, berylliosis, and tuberculosis; and aplastic anemia, hemolytic anemias, blood clotting, and AIDS as related to blood transfusion.

Renin plays a major role in the maintenance of blood pressure and is an important tool in the diagnosis and management of essential hypertension. During the past year, progress has been made in purifying inactive renin from the human kidney by the use of several new lines of monoclonal antibodies against human active renin. Further characterization of the inactive renin will continue.

Thrombolysis by urokinase and streptokinase in the early hours of coronary thrombosis has been shown to reduce cardiac injury. To reduce the threat of associated generalized bleeding, researchers have coupled urokinase to a monoclonal antibody specific for human fibrin. The enhanced local concentration increased lysis by a factor of 100 and inhibited associated systemic bleeding.

Recent studies have identified murine monoclonal antibodies that react with streptococci and myosin, implicating an autoimmune component in the cardiac muscle damage that occurs following some streptococcal infections.

Many human lung diseases are known to involve components of the host's immune system. The granulomatous inflammatory diseases include sarcoidosis, farmer's lung (hypersensitivity pneumonitis), berylliosis, and tuberculosis. One approach to understanding the mechanisms involved in granuloma formation is to determine how the immune system's components are involved in these events. In one recent study, researchers used an animal model to study how immune system mediators (soluble molecules) attract white blood cells to the site of granuloma formation, how they inhibit movement of white blood cells out of the site, and how proliferation of immune system cells already present at the site is stimulated.

Many of the inhaled substances associated with farmer's lung are complex mixtures of microbes and/or organic substances. It is thought that in these diseases the initial immune response in the lung results from reaction to a specific molecule or antigen. Efforts to analyze and purify antigens from substances known to cause these diseases have continued.

Alterations in immune-effector cell number and function and the role of these cells in the pathology of chronic interstitial lung diseases is being investigated through a multicenter study. Investigators are taking samples of fluids from patients with pulmonary fibrosis using a technique called bronchoalveolar lavage. Because specific alterations in immune components detected by bronchoalveolar lavage may be useful in the diagnosis, management, and treatment of patients, the technique is being explored as a potential clinical tool.

Transfusion-associated AIDS has stimulated the development of screening tests for blood donors. A recent 10- to 40-fold increase in sensitivity over the conventional enzyme-linked immunoadsorbent assay has been achieved with the use of HTLV-III-infected human T lymphocyte extracts in a biotin-avidin system.

In the multicenter collaborative AIDS Transfusion Safety Study, over 200,000 blood donor specimens are now being tested for antibody to HTLV-III. An extensive array of immunological tests will be performed to determine the effect of chronic blood transfusions on the immune system and any relationship between immunological alterations and the development of AIDS.

The human platelet is an important blood component in several immune disorders. Current studies of immune thrombocytopenic purpura concern the platelet surface and abnormalities of function, including identification of the platelet antigen against which antibodies are formed.

Thrombi occurring within the vasculature are the cause of heart attacks, strokes, and pulmonary embolism. Immunological methods are being used to develop probes that will aid in the diagnosis and localization of these thrombi.

NATIONAL INSTITUTE OF DENTAL RESEARCH (NIDR)

In the NIDR Laboratory of Microbiology and Immunology increasing attention is being directed to the role of T lymphocytes in chronic inflammatory diseases such as rheumatoid arthritis and periodontitis. Scientists have induced chronic inflammatory lesions in animals by injecting bacterial cell walls to demonstrate the role of T cells and their products in the development of erosive polyarthritis in joints and fibrotic granulomas in livers; animals without a thymus and without functional T lymphocytes or those treated with cyclosporine do not develop arthritis or liver granulomas. Failure to develop these lesions appears to be the direct consequence of the inability of the T lymphocytes to produce the biochemical mediators responsible for recruiting and activating inflammatory cells. A similar mediator produced by the synovial T lymphocytes of human patients with chronic rheumatoid arthritis was associated with high-intensity infiltration of their synovial tissues with mononuclear cells. When these patients were treated with leukapheresis, the production of this chemotactic factor was decreased, inflammatory cells decreased in the synovium, and the patients' arthritis improved. These studies provide evidence that T lymphocytes play an important role in chronic inflammatory diseases and that inhibition of T lymphocytes can prevent or reduce the inflammation and its effects on the surrounding connective tissue. There are active investigations on the mechanisms involved in the release of inflammatory mediators (e.g., histamine, serotonin, arachidonic acid metabolites) from basophils and mast cells. Current studies use cloned cell lines and variants that are defective in the secretory process to determine the early biochemical steps in the activation of the cells for secretion. Some of these steps include the phosphorylation of cellular proteins, activation of phospholipase enzymes, and entry of calcium into the cell. The molecules on the cell surface that bind immunoglobulins are the first step in cell activation. They are now being isolated to determine their structure and function. Such studies may lead to more effective methods for the prevention of inflammatory reactions.

Investigators in the Laboratory of Oral Biology and Physiology make extensive use of monoclonal and polyclonal antibodies in studies involving immunoblotting, ELISA, and immunogold labeling at the electron microscopic level. These techniques have been used to localize specific secretory and membrane proteins in the salivary glands and study changes in their distribution following secretory stimulation, to increase our understanding of how saliva contributes to oral health.

Current immunology research in the Clinical Investigations and Patient Care Branch focuses on the etiology and pathologic mechanisms of salivary gland involvement in Sjogren's syndrome, an exocrine gland disorder characterized by dry eyes and mouth. Studies are being carried out in mice which spontaneously develop autoimmune disease to determine the nature of salivary pathology and to identify possible autoreactive antibodies with specificity for salivary tissue. Human studies are concerned with the "autoantibody profile" of individuals with Sjogren's syndrome and the site of reactivity in the salivary glands of circulating antibodies.

The Laboratory of Oral Medicine is involved in an animal study to develop a vaccine against herpes simplex virus, using recombinant DNA techniques. Studies recently published show that the vaccine is protective in a large percentage of the animals against the development of both a lethal and latent infection with herpes simplex virus. It is hoped that continued investigations will yield a vaccine appropriate for use in protecting humans from the herpesvirus. The basic mechanisms that trigger the production of autoantibodies and the role of autoantibodies in diseases such as insulin-dependent diabetes mellitus are also being studied. Monoclonal antibodies are being used to isolate some of the autoantigens that may be involved in human autoimmune diseases.

NIDR-supported scientists are working to develop a safe and effective vaccine against dental caries for human use. They are testing combinations of antigens, adjuvants, and doses in an effort to find the most efficacious regimen.

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES (NIADDK)

The NIADDK conducts and supports research on many of the most serious diseases affecting the public health, many of which are characterized by involvement of the immune system. Significant new insights on immune mechanisms implicated in the cause or aggravation of a number of chronic diseases, including rheumatoid arthritis, insulin-dependent diabetes, inflammatory bowel disease, glomerulonephritis, and several hematologic diseases, have led to improved diagnosis and treatment and, in some cases, prevention of disease. Advances in immunology have also been applied to improving immunosuppressive regimens, thereby improving survival rates in organ transplantation.

Research results have shown that the probable cause of rheumatoid arthritis, the major crippling disorder among the rheumatic diseases, is one of a variety of agents triggering an immune reaction that later leads to chronic inflammation. Numerous studies on this and other rheumatic diseases are focusing on this sequence of events and the genetic susceptibility of some individuals to abnormal immune regulation.

Several lines of evidence suggest involvement of the immune system in insulin-dependent diabetes: the presence of islet cell antibodies and islet cell surface antibodies along with evidence of circulating immune complexes, an association with major histocompatibility antigens, and the presence of certain viral infections around the time of onset of the disease. In an exciting development, researchers have demonstrated that a transfusion of peripheral or splenic lymphocytes was able to prevent the development of the disease in diabetes-prone animals. The protective effect of the transfusion lasted for over a year in some cases.

Immunologic mechanisms have been implicated in the hereditary disease, gluten-sensitive enteropathy, which affects the lining of the small intestine and results in poor intestinal absorption of most nutrients, potentially leading to serious malnutrition. Immunologists have determined that a critical event in this disease may be the prior encounter of the immune system with a protein expressed during viral infection, later resulting in tissue-damaging immune reactions that represent a cross-reaction to that intended for a viral protein.

Researchers have made significant progress in their exploration of the role of immunologic mechanisms in the pathogenesis and treatment of chronic renal diseases, including the importance of immune complexes in the etiology of glomerulonephritis, which is characterized by inflammation of the glomeruli, the filtering units of the kidney. In another productive avenue of research, monoclonal antibody technology has successfully contributed to the investigation of cellular aspects of immune responses and kidney function.

Responses of the immune system play a key role in the success or failure of kidney transplantations. The immunosuppressive drug, cyclosporine, has been shown to be very effective in promoting graft survival in kidney transplantations. Monoclonal antibodies have been shown to reverse ongoing kidney rejection, resulting in increased graft survival and decreased requirements for immunosuppresants. In a third advance, blood transfusions with concomitant immunosuppression before a transplant significantly improved survival of the kidney graft. This procedure allows the success rate of transplantation of poorly matched living donor-recipient pairs to approach that of well-matched transplants.

Ongoing or planned Requests for Applications issued in collaboration with other institutes include: Auto-Immunity Related to Endocrine Diseases (with NIAID and NICHD); Immunopathogenesis of Diabetes (with NIAID and NICHD); Mechanisms of Allergic and Irritant Contact Dermatitis (with NIAID and CDC); and Means to Optimize Allograft Outcome of Renal Transplantation in Children (with NICHD).

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE (NINCDS)

The NINCDS supports a wide-ranging program of research addressing the immunology of the nervous system. The brain and central nervous system appear to have a unique and complex immunology; many neurological disorders involve immunological factors. Moreover, immunological techniques play important roles in neuroscience research.

Scientists in the Intramural Research Program (IRP) use immunological techniques to design individualized chemotherapy to improve the prognosis for patients with often fatal glial tumors of the brain. Specific white blood cells from the patients' tumors are incubated with the drug interleukin-2 and then injected into the tumor site. This experimental treatment and others are now under investigation; initial results are promising. Other NINCDS intramural scientists are investigating multiple sclerosis (MS). One group is characterizing the immune response to the measles virus, long thought to be implicated in MS, and is trying to understand its specific relationship to the demyelinating disorder. They have discovered differences between MS patients and others in their immunological response which may be due to an earlier measles infection. Other scientists in the IRP identified, cloned, and sequenced the gene for human myelin basic protein (MBP) and are studying the similarities between it and a mouse gene for myelin basic protein they had previously cloned. Recently these scientists discovered that there were three discrete forms of human MBP and that all three forms were coded by the same gene, an unexpected result and unusual in the genetics of the central nervous system. These studies are helping increase the knowledge of the genetic and immunologic underpinnings of MS and its natural history, and may contribute to an effective therapy.

The NINCDS supports scientists conducting neuroimmunological research in the nation's universities and research centers. A recently completed multi-institution collaborative controlled clinical trial demonstrated the effectiveness of plasmapheresis, or blood cleansing, in treating Guillain-Barre syndrome, a paralyzing disorder of rapid onset. Patients who received plasmapheresis tended to have shorter hospital stays, spent less time on respirators, and regained certain functional abilities faster than the patients who did not receive the treatment. Other scientists conducted a controlled double blind randomized pilot study of Copolymer I, an immune modulating agent, in a particular type of MS and discovered that patients who used Copolymer I had significantly fewer exacerbations than patients who received the placebo. Another group of investigators, supported by the NINCDS, have shown that humans can tolerate specific mouse monoclonal antibodies against certain subsets of T-cells active in the immune system without significant side effects. This observation implies that monoclonal antibody therapy for immune or autommune disorders, such as MS or myasthenia gravis, need not be limited by the source of the antibody.

These studies represent only a few examples of the wide range of NINCDS neuroimmunology research, investigations that are developing new knowledge of the central nervous system and its interactions with the immune system.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (NIGMS)

The NIGMS supports an interdisciplinary program in basic immunobiology as well as immunological research related to clinical investigations of the physiological responses to burn and trauma. Cells of the immune system and their products provide excellent experimental models for studying complex cell interactions, basic cellular processes, and molecular structure and function relationships. At the same time, these studies provide fundamental information on how cells of the immune system function. Furthermore, basic research in NIGMS programs on cellular biology, molecular biology and genetics strongly contributes to progress in immunology.

In addition to its support of research activities, NIGMS funds predoctoral and postdoctoral training in many areas. Approximately 15 percent of the NIGMS training budget supports predoctoral training of individuals who subsequently engage in immunology research. NIGMS also supports, via the contract mechanism, in collaboration with other NIH institutes, a Nucleic Acid Sequence Data Bank (GenBank) and a Human Genetic Mutant Cell Line Repository, which are utilized by the immunology community. NIGMS also lends its support to joint funding of immunology conferences.

In the past year, NIGMS has formed a separate, interdisciplinary subprogram in molecular immunology that transcends the major NIGMS programmatic areas of cellular and molecular biology, genetics and biophysical sciences. This subprogram directly supports research grants and a program project in areas which include: the molecular basis of immunodeficiency and inflammation; protein structure and function relationships of the cytokines, immunoglobulins, major histocompatibility complex (MHC) products, and complement; studies of cells of the immune system that pertain to membrane structure and function; regulation of cell growth and the cell cycle by cytokines, growth factors, and hormones; intracellular mediators of cell activation; the biochemical basis of cell interactions, cell differentiation and maturation; regulation of gene activation, organization and reorganization; and the genetic basis of the above cellular processes. Another NIGMS subprogram is devoted to the synthesis and structure of glycoconjugates, which constitute a major class of antigens.

Research priorities of the NIGMS include: studies of basic cellular and molecular processes using cells of the immune system and their products as experimental models; investigation of immunological mechanisms associated with skin transplantation and the physiological responses to burn and trauma; and basic immunobiology which is applicable to multiple or more general disease mechanisms.

Investigations on the structure, function and genetics of the major histocompatibility complex (MHC) encompass the role of the MHC molecules in cell recognition, the evolutionary importance of the immunoglobulin supergene family - of which the polymorphic MHC genes are members - in biological responses, the genetic specificity of the MHC antigens in immune recognition and allograft rejection, and restriction fragment length polymorphism analysis of the MHC which has been used to identify genetic loci which predispose to a spectrum of autoimmune diseases.

Studies of lymphocytes, macrophages and mast and basophil cells have shown that the coupling of a ligand to surface membrane receptors signals major physiological events, including changes in calcium flux, protein phosphorylation, membrane-cytoskeletal structure, and secretion of biochemical mediators. These investigations serve as models for basic cell biological phenomena, as well as being of importance in understanding inflammatory reactions associated with burn and trauma, wound healing, allergic responses and autoimmune processes.

Immunogenetic studies of the evolution, organization, developmental control and transcriptional regulation of immunoglobulin genes have provided important new insights into mechanisms of somatic mutation, gene recombination, control of gene activation via enhancer and promoter region function, and the mechanisms of tissue specificity via trans-acting protein factors. The results of these studies are of considerable importance for understanding basic genetic control mechanisms, as well as providing the molecular basis for the great diversity of antibody responses and delineating events at the gene level in cells undergoing differentiation.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD)

The NICHD is studying patients and animal models to better understand immune control mechanisms and therapeutic methods for various immune deficiencies, including severe combined immunodeficiency in children. Abnormalities in adenosine and deoxyadenosine metabolism that suggest other disorders of purine metabolism have been detected in biochemical studies of the pathogenesis of this disease.

Studies in laboratory animals have shown that zinc deficiency causes a decrease in antibody responses, especially with regard to antigens requiring T helper cell function. It is also known that the ontogenic development of the immunologic system is slowed or stopped when zinc deficiency occurs during fetal or early postnatal development. Functioning of thymic inductive factors, maturation of T cells and B cells, and levels of corticosteroids may all be affected in this situation.

Studies of the mammary gland have led to exciting information concerning distribution, origin and function of different cellular and soluble components in breast milk and how they affect immune function of the newborn. These investigations have also described the contribution of bronchus- and gut-associated lymphoid tissue to immunocompetence of secretions of the mammary gland.

Current information indicates that active maternal immune responses occur following early recognition during pregnancy, thus providing selective benefits to the fetoplacental unit from the time of implantation to parturition. The strict genetic control of these responses by genes associated with the major histocompatibility complex is being studied.

Studies clearly suggest that autoimmunity may be a significant factor in the etiology of infertility. In the mouse, it has been reported that susceptibilities for orchitis and vasitis are under separate genetic controls. If confirmed in man, such knowledge might be useful in evaluating candidates for vasectomy with respect to the risk of permanent infertility. In other studies, the experimental immunization of female rabbits with proteins from the outer layer of the egg resulted in a complete loss of maturing follicles and gonadotropin-induced progesterone secretion. This suggests that one aspect of immunologic infertility may be impaired ovarian function as a result of autoimmune disease.

Significant progress in the area of immunocontraception has occurred principally in research on the immunology and immunochemistry of the zona pellucida (ZP) of the egg and of human chorionic gonadotropin (hCG). Studies on ZP and hCG are aimed at the induction of immunity, directed specifically at these targets, that is of sufficient intensity and duration to inhibit the involvement of the former in fertilization, and to "neutralize" the latter. Since both ZP and hCG are "pregnancy unique," immunity directed specifically against them may not have harmful side effects in other parts of the body. Some progress has been made in the identification, characterization, and location of epitopes on both structures. The purpose of such classification of epitopes is the identification of those that may be used in the induction of "appropriate" immune responses. One laboratory has reported significant progress in the theoretical specification of the type of antibody that will neutralize hCG without affecting other components of the body. Other laboratories have recently begun to apply new concepts of anti-idiotypic immunity to the development of highly specific responses directly against ZP and hCG.

One of the potentially most important recent applications of the new immunotechnology is the development of a highly specific immunoradiometric assay for hCG in urine. Since hCG is secreted by the early embryo as well as certain tumors, this new assay is already being used for: 1) the detection of pregnancy at much earlier stages than heretofore possible; 2) the early detection of ectopic pregnancy; and 3) the early detection of gestational trophoblastic neoplasms.

The intramural Laboratory of Developmental and Molecular Immunity conducts research on the developmental and molecular biology of "natural" and immunization-induced immunity to bacterial and other antigens. Emphasis is placed on the study of pathogenic mechanisms, vaccine development, and immunoregulatory mechanisms of the young host. A scheme has been devised to covalently bind tetanus toxoid to the capsular polysaccharide of H. influenzae type b. The resultant compound was found to be considerably more immunogenic than the unbound polysaccharide and to elicit booster responses in infant primates; a collaborative clinical trial is planned. The immunogenicity and safety of a typhoid vaccine based on a purified capsular polysaccharide of S. typhi has been demonstrated in normal volunteers between 5 and 70 years of age in this country, France and Nepal; a collaborative double-blind field trial to investigate efficacy is now in progress in Nepal.

NATIONAL EYE INSTITUTE (NEI)

Ocular immunologists supported by the NEI continue to make significant progress in investigating those areas identified as NEI research priorities in the 1984 NIH Report on Immunology Research. Several investigators are currently involved in the characterization of the role of autoantigens in chronic corneal, retinal, and choroidal inflammatory disease. These studies have suggested that several immunopathogenic antigens in the retina, retinal pigment epithelium, choroid, and optic nerve may be responsible for the autoimmune intraocular inflammation known as uveitis. At present only one of these antigens, S-antigen, has been sufficiently purified to demonstrate its ability to induce uveitis. Researchers now have evidence that membrane-bound components in the rod outer segments are an unusually rich source of antigenic proteins, other than S-antigen. Attempts are now being made to purify at least two of these proteins to test their immunopathogenic activity in animal models.

The cellular and humoral events that result from the presence of autoantigens and contribute to the inflammatory process are also being studied. Monoclonal antibodies are being used to analyze T lymphocyte subsets in that process. Monoclonal antibodies are also being used in the localization and characterization of cell-surface antigens involved in various inflammatory conditions of the cornea.

The effectiveness of the anti-inflammatory drug cyclosporine in the treatment of uveitis is under investigation by intramural researchers of the NEI in a randomized, masked, clinical study. Evaluation of topical administration of cyclosporine in an animal model with experimentally-induced autoimmune uveitis is also in progress.

Herpes simplex virus (HSV) infection of the cornea is responsible for most corneal blindness in this country. Although the initial infection may subside after treatment, nearly 25 percent of those infected experience a recurrence of the epithelial disease or a complication of the infection in the stromal layer of the cornea within two years of the initial infection. Several NEI-supported studies are designed to elucidate the mechanisms involved in the progression of HSV keratitis into latency or dormancy and the eventual reactivation of latent virus responsible for the recurrent disease. These studies include characterization of the viral genome during latent and reactivating infection and elucidation of the complex interaction between viral antigens and the host immunopathogenic response during latency and reactivation. The feasibility of producing a HSV vaccine is also under investigation. A study is testing the hypothesis that infection of the trigeminal ganglia, a group of nerve cells known to harbor the latent virus, with a live, attenuated or inactivated form of the virus will prevent secondary infection by the virulent form of the virus.

An improved method for delivery of antiviral drugs to the site of HSV infection is also being evaluated. Liposomes containing a variety of antiviral drugs which have specific antibody against HSV on the surface are being constructed. These immunoliposomes should attach specifically to virus-infected cells and allow drug release in a high local concentration for a prolonged period. This should inhibit viral replication close to the attachment site and reduce the required frequency of topical administration required for effective treatment.

Because corneal allograft rejection is a leading cause of graft failure, research is currently aimed at gaining an understanding of the rejection process and attempting to modify or eliminate it. Corneal allografts that have been soaked in a solution containing antibody against the histocompatibility or human lymphocyte antigens (HLA) found on the surfaces of most tissues have been shown to have an increased survival time when compared to unsoaked grafts. The immunologic basis for this protection of allografts by soaking in antibody solution and the biological characteristics of the histocompatibility antigens on the surface of the cornea are currently being studied. The effect of HLA matching of donor corneas with recipient tissue on the outcome of the allograft is also being evaluated.

A number of researchers are using immunochemical and biochemical techniques to study lens components in normal and pathological states. These studies include ultrastructural, biochemical, and immunological characterization of the zonular fibers--the elastic fibers which support the lens. Investigation of the normal state of these fibers will provide valuable information on the abnormal conditions which lead to lens dislocation and pseudoexfoliative syndrome, a condition in which a flaky translucent substance is deposited in the lens capsule.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS)

The NIEHS supports studies on the effects of environmental pollutants on the immune system. Its Extramural Program provides support in this area through research project grants, program project grants, and multidisciplinary components of core center grants. The Toxicology Research and Testing Program supports contracts to screen and evaluate potentially immunoalterative chemicals or drugs as part of the efforts of the National Toxicology Program (NTP) in carcinogenicity and toxicity testing. The Intramural Research Program (IRP) performs laboratory investigations in this area.

Environmental agents may adversely affect the immune system in a variety of ways; the two most important manifestations, however, are suppression of the immune system resulting in immunodeficiency, and immunoenhancement resulting in hypersensitivity, allergy or autoimmune disease.

The NIEHS supports immunological research via the grants mechanism on a variety of environmental agents including industrial chemicals, pesticides, heavy metals, gaseous pollutants, natural toxins, and minerals such as asbestos and silica. It also supports studies on: immunological method development to characterize immune responses to environmental agents; the effects of gases and particulates on pulmonary hypersensitivity and phagocytosis; the role of inflammation in promotion of tumor development; effects of metals on lymphocyte function, immunoglobin synthesis, and T cell activities; alteration of humoral and cellular responses in asbestosis in humans; and mechanisms of chemically-induced immune dysfunction investigated at the cellular and molecular levels.

Through the NTP a contract was awarded recently to assess the potential of, and extent to which, various environmental pollutants cause secondary immunodeficiency disease and allergic hypersensitivity. Studies currently in progress include: examination of the influence of tetraethyl lead and gallium arsenide (and related compounds) on immune function and host resistance in mice, and evaluation of glutaraldehyde and 4-nitrophenyl-pentadieneal (NPPD) as chemical sensitizers (allergy) in guinea pig and mouse models. Once results are available from these studies, they will be included with NTP carcinogenicity and other toxicity data for use in human risk assessment.

The IRP continues to focus on research in applied immunology regarding issues related to chemical pollutants. Fibrotic lesions in the lung associated with exposure to asbestos, which are an early manifestation of disease, for example, have been demonstrated to be immunologically mediated. This could provide opportunities for immunotherapeutic intervention in asbestos-related lung disease. Another area of intense investigation has been elucidation of the mechanisms responsible for immunosuppression caused by dioxin, the toxic component of the herbicide "Agent Orange." Another study recently completed involved methyl isocyanate (MIC), responsible for the deaths of 2,000 individuals in Bhopal, India. Because nonlethal exposure of many individuals also occurred, NIEHS studied MIC in laboratory animals as a model for its potential to alter the immune system, particularly as it pertains to lung infections in exposed humans. Studies to determine the potential of MIC to cause allergic lung hypersensitivity are being coordinated in collaboration with NIAID.

NATIONAL INSTITUTE ON AGING (NIA)

The NIA supports basic research that focuses upon immunosenescence in the aged organism. These objectives are reached by a diverse program supporting both extramural and intramural research on the phenomena that characterize the aging immune system, the mechanisms that mediate the age-related changes, and the clinical implications of these changes in the elderly.

There are impairments in monocyte-B cell interactions in many elderly subjects. In certain individuals, the diminished B cell proliferative responses represent a combination of defects in both the B cell and the monocyte compartments, while in others the impairment lies either in the B cells or the monocytes. It appears that B cell activation is directly supported by monocytes of certain predominant HLA phenotypes, especially when antigen challenge is pulsatile rather than continuous. This may be related to the observation that in the elderly subjects there is a deficit in IL-1 production which is overcome when monocytes are optimally stimulated. Exogenous IL-1 and IL-2 can improve diminished B cell activation and proliferation although impairments in IgM production still exist.

T cells from elderly humans are impaired in their capacity to produce IL-2 and to express a functional receptor for IL-2. IL-2 secretion by peripheral blood T cells depends upon cross-linking and modulation of membrane surface T3 molecules as well as additional and as yet undefined accessory cell signals. Expression of IL-2 receptors and the proliferation of T cells can be induced in the absence of these signals if exogenous IL-2 is provided.

Nuclei from lymphocytes from young and old humans have been isolated and their response to cytoplasmic signals for DNA replication compared. While comparable amounts of these cytoplasmic factors are produced by the young and old lymphocytes, the nuclei from the old donors are significantly impaired as contrasted to those from the young donors.

The production of autoantibodies, such as anti-gamma-globulin, anti-DNA, anti-thyroglobulin and anti-rheumatoid factor have been reported to increase with aging. It appears that low levels of autoantibodies exist in young normal individuals but with aging the immunoregulatory mechanism for control of bone marrow B cells, possibly a mechanism requiring IL-2 dependent T cells, can become aberrant and result in increased expression of autoreactive B cells.

Activation of B cells can be accomplished without bringing the B cell into a division cycle; B cell activating factors can act on G_0 cells which have been activated by membrane receptor binding agents. Activation of B lymphocytes proceeds through a calcium dependent phosphokinase system. The effect of the activation process is to translocate the enzyme from cytoplasmic loci to the membrane which then allows the activated cell to differentiate.

As part of an ongoing long-term collaborative prospective study on the normal aging process, it has been found that peripheral blood lymphocyte levels decline significantly in the last 3 years of a person's life. This change is able to be seen in healthy individuals with no signs of a fatal disease.

NIA intramural scientists are collaborating with NCI scientists to provide aged human activated lymphocytes to isolate mRNA for the IL-2 gene. They are also working with extramural scientists funded by NIAID and NCI in studies of AIDS, and there is planned collaboration with an NIAID-sponsored trial of influenza vaccines in the elderly.

DIVISION OF RESEARCH RESOURCES (DRR)

The DRR supports immunology research through five resource-related programs. The General Clinical Research Centers Program includes: trials of therapies for immunodeficiency and hyperimmune diseases; studies of the pathogenesis of immune dysfunction; and assessment of immune response to allergens, steroids, and drugs. The Shared Instrumentation Grant provides sophisticated instruments as a shared resource for NIH-supported investigators. Cell sorters and electron microscopes, for example, are used for studies of cell surface receptors, lymphocyte differentiation, and characterization of T cell subsets. Animal models of immune disease and conditions, such as AIDS and infertility due to antisperm antibodies, are supported by the Animal Resources Program. The Biomedical Research Technology Program develops and provides state-of-the-art instruments and methodologies for biomedical research. These are applied to immune studies such as: molecular mechanisms of histamine response, conformation studies of antibody sites, and antigen/antibody interaction. Minority scientists investigating immune response to toxins, tumoricidal activity of macrophages, and immune aspects of sickle cell disease, are supported through the Minority Biomedical Research Program.

CENTERS FOR DISEASE CONTROL (CDC)

Immunology research is conducted by a number of the CDC component Centers. The CDC, in collaboration with the Arthritis Foundation, sponsors a laboratory for anti-nuclear antibody serology. This laboratory identifies, formulates, calibrates and distributes reference sera with defined specificities for distinct antigens. This laboratory also serves as the reference serology laboratory for a multicenter (cooperating clinics) study of undifferentiated connective tissue diseases as well as clinical studies conducted with the rheumatic disease group at Emory University. Immunologic studies of AIDS are conducted in several areas: immunologic support of epidemiologic studies; clinical studies of HTLV-III infection; in vitro interactions of HTLV-III with cells of the immune system; and the immunologic (host) response to HTLV-III infection. The CDC is also involved in the evaluation of cell-mediated immune mechanisms required for resistance to, or clearance of, virus infections, and in studies of mechanisms mediating immune damage associated with virus infections, and control mechanisms which prevent immunopathology.

FOOD AND DRUG ADMINISTRATION (FDA)

Immunology is one of the areas that has recently received increasing attention and resources for research within the FDA Office of Biologics Research and Review (OBRR) due both to the interactions of many therapeutic agents with the immune system, and to the increasing number of immunological preparations such as monoclonal antibodies being submitted for review and use in human trials. The OBRR devotes approximately 36 percent of its research budget to immunology programs, which include laboratories in the Divisions of Biochemistry and Biophysics, Bacterial Products, Blood and Blood Products, and Virology. Projects are ongoing in collaboration with several of the NIH institutes, and also with university and other laboratories around the country and abroad.

The programs involve research in areas including: 1) a number of aspects of induction and regulation of immunity to viruses including (Epstein-Barr virus (EBV), cytomegalovirus, herpes, influenza, polio and measles); 2) T cell activation, and recognition of protein antigens by T lymphocytes in both animal and human systems; 3) expression of immunoglobulin idiotypes, and use of idiotype manipulation for induction of immunity to pathogens; 4) immune responses to histocompatibility antigens; 5) development of immunity to bacterial polysaccharide antigens; 6) antigen presentation by human lymphocytes; 7) interactions of interferons with their receptors; 8) activation of monocytes by physiologically important substances; and 9) production of IL-2 cells of human patients.

In addition, a number of projects are ongoing in the area of AIDS research. These include: 1) attempts to induce protective immunity to HTLV-III by a variety of means; 2) efforts to characterize the immunologically important determinants on the virus; 3) studies of the interactions of AIDS with EBV infection; and 4) studies of various immune functions in AIDS patients and in asymptomatic virus-positive individuals. Antibodies against an envelope protein of HTLV-III have been developed, which may be useful in screening for the presence of the virus and may help to identify possible neutralizing sites on the surface of the virus which could be the target of an AIDS vaccine. Much of the AIDS-related research involves collaboration with groups involved in clinical trials.

The genes responsible for capsular polysaccharide production in the bacterium, Escherichia coli, strain K1, have been cloned, a system for capsular typing has been developed, and proteins responsible for bacterial virulence have been delineated. Polysaccharide-protein conjugates have been studied as potential vaccines.

ALCOHOL DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION (ADAMHA)

The three institutes of ADAMHA -- the National Institute of Mental Health (NIMH), the National Institute on Drug Abuse (NIDA), and the National Institute on Alcohol Abuse and Alcoholism (NIAAA) -- all have substantial extramural and intramural research efforts focusing on the immune system.

The major focus of NIMH research has been on the relationships between psychological conditions, psychiatric illness, and the immune system. Research is supported which explores how psychosocial factors may affect immune system function and how behavioral interventions may optimize functioning of the immune system. Illustrative of this interest are projects studying the psychological and behavioral consequences of having suspected or diagnosed AIDS. In a collaborative effort with NIAID, a prospective longitudinal study of homosexual men is being supported to develop information relative to the development of AIDS and to relate serological and immunological factors with psychological factors. Relationships between the immune system and mental disorders are being supported in NIMH studies of the immune system in schizophrenia, major depressive disorders, and high levels of psychological stress. One investigator is developing a nonhuman primate model for assessing the effects of psychologically induced stress on immune responses to document the qualitative and quantitative effects of elevated cortisol levels on basic immune parameters. Another investigator is exploring the association between clinical depression and immune function to better understand ways in which the central nervous system regulates immunity.

The NIDA supports basic immunological research related to the action of opiates and other drugs on the immune system. Other studies include: the effect of marijuana on the neurological and immunological systems in guinea pigs; the immuno-suppressive effects of marijuana smoke on susceptibility to microbial infection and tumor growth in rats; and the effects of narcotics on the lymphocytes of addicts. Using in-depth interviews, assessments of immune and virological conditions, and complete medical evaluations, a study will evaluate the risk factors for AIDS associated with drug use. A follow-up study will focus on changes in the individual's health to determine the relationship between AIDS and immunological status, virological profile and drug abuse lifestyle.

The NIAAA supports research into the effects of alcohol on the immune system. This research derives from the clinical observation that alcoholics have an increased incidence of infectious diseases, raising the question of whether alcohol may impair the function of the immune system. Intramural scientists are studying the effects of alcohol on immunocompetency in an animal model. Preliminary findings indicate that administration of alcohol in doses sufficient to produce dependence in one week results in changes in the immune system consistent with a functional impairment of the immune system. In another intramural study, alcoholic patients and controls are being evaluated to determine the effects of long-term alcohol abuse and withdrawal from alcohol on the immune system. Projects currently supported by the extramural program include research into the role of alcohol as a suppressant of pulmonary antibacterial defenses. Increased susceptibility to bacterial pneumonia has been described among alcohol abusers for decades, although there has been little direct experimental evidence to explain the altered resistance to such infection in alcoholics. Current research is defining and comparing the suppressive activities of acute intoxication and chronic alcohol consumption on pulmonary defense mechanisms.

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

The HRSA conducts immunology research related to leprosy at the Gillis W. Long Hansen's Disease Center in Carville, Louisiana. THe NIAID funds projects there to study the antigenic make-up of Mycobacterium leprae, the causative organism of leprosy, using monoclonal antibodies, and to study the interactions of macrophages with M. leprae. A collaborative project of the Hansen's Disease Center and the Schieffelin Leprosy Research and Training Center in Karigiri, India is investigating the role of "transfer factor" in the immunotherapy of leprosy. The NIH funds a project to determine optimum vaccination procedures for human leprosy vaccines. The Hansen's Disease Center, in collaboration with FDA, CDC, and the Leprosy Mission in India, is planning a field test of three leprosy vaccines, involving 1.2 million Indian subjects in Andra Pradesh. Vaccinations will begin in 1988 and the assessment of the field trial test will conclude in 1995.

VETERANS ADMINISTRATION (VA)

The VA conducts a broad based research program in the area of immunology and diseases related to immune dysfunction. While VA research in these areas includes both basic and clinical research studies, the concentration of research resources in the VA is in the area of clinical research. These studies are supported by the VA's Medical Research Service, many in collaboration with NIH. The areas that are under study include: 1) mechanisms to enhance human allograft acceptance; 2) the basic mechanisms underlying autoimmune diseases; 3) the mechanisms underlying other immune-related diseases; 4) the interface between immune function and infectious diseases, including studies of the mechanism and potential treatment of AIDS; 5) the application of immunological techniques such as the development of monoclonal antibodies to improve diagnosis and treatment of selected cancers; and 6) immune changes in the aging process. Examples of current and planned VA clinical studies are: 1) an evaluation of a possible etiological role of Coxsackievirus B in polymyositis; 2) the use of monoclonal antibodies against human helper T cells as a therapeutic strategy in the treatment of autoimmune diseases; 3) an analysis of the possible role of immune dysfunction in chronic hepatitis; and 4) a clinical evaluation of several possibly effective antiviral agents in the treatment of AIDS.

CONCLUSIONS

In February 1984, the NIH submitted a report to the Committee on Appropriations on immunology research. That report described in detail the relevance of immunology to each of the NIH institutes, and to many diseases under study. It stated the priorities of each of the NIH institutes for immunology research.

Since the 1984 report, significant progress has been made in carrying forward the research priorities discussed there. This report has detailed immunology research priorities, progress, and current and planned activities, including collaborative clinical applications, of the NIH institutes, as well as other PHS agencies and the VA.

Among the diseases covered in this report are: acquired immunodeficiency syndrome (AIDS); alcoholism; allergies; aplastic anemia; arthritis; asbestosis; asthma; atherosclerosis; berylliosis; cancer; coronary heart disease; dental caries; diabetes mellitus; glomerulonephritis; gonorrhea; Guillain-Barre syndrome; hepatitis; herpes; hypertension; immune thrombocytopenic purpura; infertility; inflammatory bowel disease; influenza; leprosy; leukemia; lymphoma; malaria; measles; multiple sclerosis; myasthenia gravis; narcotic addiction; orchitis; periodontitis; polymyositis; pulmonary fibrosis; rheumatic heart disease; sarcoidosis; schizophrenia; sickle cell disease; Sjogren's syndrome; systemic lupus erythematosus; tuberculosis; typhoid fever; urticaria; uveitis; and whooping cough.

Immunology is one of the broadest areas of research supported by NIH, with relevance to many diseases and to every one of the NIH institutes. The NIH institutes have responded to opportunities in this field in a well-coordinated manner. Research advances have already found applications in the clinical setting and have opened new areas of investigation. In order to generate new knowledge crucial to future breakthroughs in immunology, it is essential that the NIH continue to support basic and clinical research in this field.

NIH Funding Supporting Basic and Clinical Immunology

(Dollars in thousands)

	1985 Actual	1986 Approp.	1986 Revised Estimate	1987 Estimate
NIAID..................	$140,904	$141,231	$134,575	$130,382
NCI....................	133,112	135,700	130,700	129,600
NHLBI..................	57,427	61,387	57,926	56,133
NIDR...................	5,137	5,399	5,166	4,959
NIADDK.................	79,431	84,650	80,150	78,100
NINCDS.................	17,552	19,200	17,951	17,761
NIGMS..................	5,000	6,000	6,000	6,000
NICHD..................	22,556	23,700	22,200	22,400
NEI....................	17,801	19,500	18,000	18,000
NIEHS..................	5,022	5,204	5,003	4,923
NIA....................	10,640	11,792	11,038	10,824
DRR....................	25,631	25,686	24,581	21,077
TOTAL..............	520,213	539,449	513,290	500,159

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

National Institute of Arthritis, Diabetes,
and Digestive and Kidney Diseases

REPORT ON AN EVALUATION OF THE PROPOSAL TO ESTABLISH KIDNEY AND UROLOGIC DISEASES RESEARCH CENTERS

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REPORT ON AN EVALUATION OF THE PROPOSAL TO ESTABLISH KIDNEY AND UROLOGIC DISEASES RESEARCH CENTERS

Executive Summary

In House Report No. 99-289, the Committee on Appropriations requested an evaluation of the proposal to establish up to six Kidney-Urology Centers focusing on: (1) hypertension and the kidney; (2) diabetes mellitus and the kidney; (3) obstructive and hereditary diseases of the urological system and the kidney; (4) nutrition and the kidney; (5) immunology and the kidney; and (6) cellular injury and the kidney. The following report is submitted in response to that request.

The National Institutes of Health has evaluated the scientific feasibility and potential benefit of establishing a kidney and urologic diseases research centers program within the National Institute of Arthritis, Diabetes, and Dagestive and Kidney Diseases (NIADDK), the Institute with primary responsibility for research efforts in these fields.

The goal of such a centers program would be the reduction of the major causes of kidney and urologic diseases by the early 1990s. The proposed program would focus on end-stage renal disease (ESRD) and benign prostatic hyperplasia (BPH). As the U.S. population ages, both of these diseases are increasing in frequency. ESRD and BPH have combined annual costs in excess of an estimated $4 billion, and their costs are increasing steadily. It has been estimated that intensification of research on these diseases through a centers mechanism could reduce by approximately 20 percent the number of patients entering the Federal End-Stage Renal Disease Program or requiring therapies for benign prostatic hyperplasia at an estimated savings of $1 billion annually.

Current treatment approaches to ESRD and BPH are only palliative. They deal solely with the complications of an already fully developed disease process. For ESRD, available therapies are kidney dialysis or transplantation. For BPH, surgical techniques are used to remove glands which have become pathologically enlarged. In both cases, current means of clinical management are expensive and do not offer either prevention or cure.

At the same time, emerging research opportunities in kidney and urologic diseases offer considerable promise of generating new knowledge to combat ESRD and BPH through strategies aimed at early diagnosis and prevention. Each of the areas in which centers are proposed offers compelling research challenges and opportunities which could be pursued effectively through the centers mechanism. There is reason to believe that a sufficient number of talented researchers would apply for kidney and urologic diseases research centers grants, if the opportunity existed. Thus, the quality and scientific merit of center grant applications could be expected to be high and the competition for awards quite rigorous.

NIH experience with specialized research centers suggests that they can provide a valuable means of focusing investigations on a given topic or disease. The proposed centers would aim to foster multidisciplinary and interdisciplinary research efforts, which would complement the regular research grant mechanism by attracting a greatly needed cadre of new biomedical research investigators to the kidney and urologic diseases fields.

The concept of research centers in kidney and urologic diseases is strongly supported by the academic research and clinical communities in these fields and by the National Kidney Foundation. It is also consistent with recently enacted authorizing legislation.

Based on an evaluation of these considerations, there is sufficient reason to believe that the proposed centers program is scientifically feasibile and that it would contribute positively to advances in research knowledge and therapeutic approaches relative to ESRD and BPH. The NIH is therefore supportive of the concept of kidney and urologic diseases research centers, if additional resources were to be made available for this purpose.

REPORT ON AN EVALUATION OF THE PROPOSAL TO ESTABLISH KIDNEY AND UROLOGIC DISEASES RESEARCH CENTERS

INTRODUCTION

In its report on the Fiscal Year 1986 budget for the Department of Health and Human Services, the House Committee on Appropriations stated:

> "The center concept might provide the necessary framework and mechanism for the kidney-urology community to intensify the research advances to prevent dialysis and transplant treatment for many citizens. The Committee requests an evaluation of the proposal to establish up to six multidisciplinary, inter-institutional kidney-urology centers to be funded after employing the usual and customary processes of the Nationax Institutes of Health to insure the quality and scientific merit of the proposals received. Those centers would be: hypertension and the kidney, diabetes mellitus and the kidney, obstructive and heredity diseases of the urological system and the kidney, nutrition and the kidney, immunology and the kidney, and cellular injury and the kidney." (House Report No. 99-289, page 51)

The following report has been prepared by the National Institutes of Health of the Department of Health and Human Services in response to this request.

BACKGROUND

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) has the lead responsibility for NIH research efforts in kidney and urologic diseases. Within NIADDK, the Division of Kidney, Urologic and Hematologic Diseases supports basic, clinical, and applied aspects of research by several mechanisms including investigator-initiated research grants, research contracts, and awards for the development of new investigators. The Division does not currently have a centers program.

The NIH has evaluated the concept of establishing kidney and urologic research centers within NIADDK and has concluded that research could be expected to benefit from a multidisciplinary and interdisciplinary approach provided by the centers research mechanism.

In the evaluation of the feasibility and potential benefits of establishing kidney and urologic diseases research centers, the following were considered: (1) the magnitude of the health problems such centers would address; (2) the current state of research and treatment; (3) research opportunities that centers might pursue; (4) specific research emphases of possible centers; (5) expertise and interest of potential center grant applicants; (6) beneficial characteristics of the centers approach; (7) recommendations of professional and voluntary organizations in the kidney and urologic fields; and (8) recent authorizing legislation related to the centers concept. Each of these areas is discussed in this report.

MAGNITUDE OF THE HEALTH PROBLEMS

As a first step in evaluating the feasibility of kidney and urologic diseases centers, consideration was given to the extent of the health care problems such centers would address, namely, end-stage renal disease (ESRD) and benign prostatic hyperplasia (BPH). These two conditions account for increasing social and economic costs in the United States. It is thus imperative that means be sought to prevent and more effectively manage these disorders.

The scope of the health care problems is reflected in the direct costs of ESRD and BPH to the Federal Government and the public--over $4 billion annually. There has been a steady 10 percent annual increase in the number of patients entering end-stage renal disease. This number is expected to increase for at least the remainder of this century. The data are equally disturbing for benign prostatic hyperplasia. At present, more than one-half of men over the age of 50 and nearly all men over the age of 70 are affected by BPH. As the U.S. population progressively ages, BPH will affect an increasingly large percentage of the population.

Thus, the magnitude of the health care problems posed by ESRD and BPH provides a strong rationale for intensifying research on these diseases through a mechanism such as centers.

CURRENT RESEARCH AND TREATMENT

The main focus of research on ESRD and BPH has been the treatment of the fully developed diseases, that is, renal dialysis or kidney transplantation for end-stage renal disease, and surgical techniques for the removal of glands which have become pathologically enlarged due to benign prostatic hyperplasia. These interventions now are established as useful and appropriate techniques in the management of the end stages of these two diseases. Unfortunately, these strategies are expensive and are only palliative. They do not offer either prevention or cure.

To date, research investigators have concentrated very appropriately on problems of the acute treatment of patients who are facing death or a serious impairment of health as a result of losing the function of the affected organ. In the case of end-stage renal disease, this objective has been met in the development and refinement of several methods for addressing the loss of renal function through dialysis and/or transplantation. In the case of prostate diseases, the original therapy has been removal of the prostate. These procedures, however, are associated with significant morbidity and considerable individual, societal, and economic costs. Therefore, it now seems appropriate that the next phase of research be established, namely, the initiation of research efforts to enable diagnosis of the early stages of disease and to prevent or arrest progression of disease beyond those early phases.

RESEARCH OPPORTUNITIES WHICH CENTERS COULD ADDRESS

For the first time, it appears that there are research opportunities for eliminating or reducing end-stage renal disease and certain urologic diseases such as benign prostatic hyperplasia. These come at a time when the costs for treatment are continuing to escalate. A centers program could be effective in addressing two research areas: (1) fundamental research in kidney diseases and urology would benefit from being broadened scientifically and encouraged to focus on end-stage renal disease and benign prostatic hyperplasia, and (2) improvements could be made in effectively translating current knowledge about fundamental biological processes and treatment needs into the practice of medicine.

Two new exciting avenues of research that have recently been pursued in animals could now be applied to ESRD and BPH:

- o ESRD: Investigators have been able to show that manipulation of kidney function by relatively simple and non-invasive means such as drugs and diet can halt the progression of renal disease in rats. This was demonstrated in a variety of renal diseases, including that due to diabetes mellitus. These data have been confirmed and represent the first meaningful lead in the search for methods to halt the spiraling social and economic costs of treating end-stage renal disease.

- o BPH: The receptors for testosterone (an androgen) have been the focus of research proposed by investigators who are excellent scientists and have been newly recruited to the study of the prostate. Since androgens are thought to be a major factor in the cause of benign prostatic hyperplasia and these investigators are experts in the study of cellular effects of similar molecules, it is likely that these findings can be exploited to result in significant advances in prostate research.

The present body of knowledge about ESRD and BPH has largely been developed through single investigator-initiated research grants and a very small NIADDK contract program. As new scientific knowledge accumulates, groups of investigators brought together through a centers program could apply this knowledge base to research into the early diagnosis and prevention of these diseases. Thus, the centers concept is considered scientifically feasible based on such indices as the state-of-the-art science in kidney and urologic diseases as reported in scientific journals; presented at conferences, workshops, and symposia; discussed by working scientists with relevant NIH program staff; and other mechanisms.

SPECIFIC RESEARCH EMPHASES OF PROPOSED CENTERS

As noted previously, the research centers concept under evaluation would focus on the major causes of ESRD and BPH. For ESRD, these include renal hypertension, diabetes mellitus, hereditary and environmental factors, and immunologic diseases. The basic mechanisms of kidney disease include cellular dysfunction, vascular disease, exposure to toxins, and genetic disorders. For BPH, major causes are acquired disorders impeding the normal drainage of the urinary tract. These areas are discussed below.

Hypertension: In the United States, hypertension is the leading cause of kidney failure and accounts for 24 percent of all patients entering the End-Stage Renal Disease Program. It is now clear that hypertension can occur as a systemic phenomenon or can be restricted only to the kidney. The latter type of hypertension leads to rapid renal failure, which, until recently, has been undetectable in its early stages. It is imperative that the causes and treatment of the renal mechanisms underlying the hypertension be identified.

Diabetes Mellitus: The cause of kidney disease in diabetes mellitus is an important unresolved question. Kidney failure is the major cause of morbidity in diabetes mellitus and accounts for 23 percent of all new patients entering end-stage renal disease. The frequency of renal disease in diabetes mellitus increases in direct proportion to the length of time that a patient has been diabetic. Thus, as medical care improves life span, the incidence of renal failure can be expected to increase. Finally, dialysis and renal transplantation therapies are more hazardous in diabetic than non-diabetic patients. For all these reasons, it is clear that the means to prevent or halt the progression of renal disease in diabetes mellitus needs to be developed. Animal experiments suggest that the means may be at hand to accomplish these objectives. In fact, diabetic renal disease has been reversed or prevented in animals through currently available methods of dietary and drug intervention.

Obstructive and Hereditary Diseases of the Urologic System and the Kidney:

o Genetic or Heritable Kidney Diseases: In these diseases, substantial progress has been made with a modest investment. The chromosomal location of the gene for polycystic kidney disease has recently been identified. This information has immediate clinical significance for the detection of disease carriers, thereby raising the possibility of designing treatments which may interdict the current inexorable progression of these diseases to kidney failure and to dialysis or transplantation therapies.

o Obstructive Diseases of the Urinary Tract: These diseases, which include benign prostatic hyperplasia, account for a large fiscal and personal drain on the U.S. population. Research advances regarding the potential causes of BPH, such as the isolation of testosterone receptors and molecules responsible for abnormal cell growth, are now at hand. These findings may produce near-term results if research is expanded and focused specifically on the prostate.

Nutrition and Toxins: The effects of nutrition and toxins are another area deserving increased emphasis. The NIADDK has already initiated a study of the effects of dietary restriction of protein intake on the progression of renal disease, in collaboration with the Health Care Financing Administration. This study is based on animal studies which showed that protein restriction reduces the workload of the kidney and prevents or substantially slows the deterioration of renal function in animals with kidney failure. If this proves true for humans, the savings in money, time, and human suffering would be substantial. This study is being partially supported by the private sector, and if successful, may result in full private sector support. Other nutritional and environmental factors must be studied for their roles in the initiation or potentiation of renal disease.

Immunologic Renal Disease: There are currently more than 70,000 patients with end-stage renal disease. Transplantation is the preferred therapy for a large number, but immunologic factors either preclude transplantation or result in early rejection of the transplanted organ. Many new advances in basic immunology could now be applied to this problem. One example is the recent use of monoclonal antibodies directed against the lymphocytes which are responsible for rejection of the renal transplant. Preliminary data suggest that such approaches hold promise not only of increasing the numbers of patients who can be transplanted, but also of increasing graft survival once they receive new kidneys. The medical, societal, and fiscal implications of even a modest improvement in the current management of end-stage renal disease would be substantial. These same advances in the understanding of basic immunology also hold promise for the prevention or more effective treatment of renal diseases caused by derangements of the immunologic system.

Renal Failure Resulting from Cell Injury: The leading cause of death in post-surgical patients is renal failure due to cell injury. This is also a serious problem in patients subjected to major trauma. In fact, over 50 percent of such patients ultimately succumb. Thus, the identification of basic biologic processes that lead to cell injury is a high research priority.

EXPERTISE AND INTEREST OF POTENTIAL CENTER GRANT APPLICANTS

Based on interactions with investigators in the research community, the NIH is aware that a sufficient number of highly talented and interested researchers would likely apply for a kidney and urologic diseases research center grant, if the opportunity existed. Many of these investigators are highly skilled in the use of new immunologic, genetic, and other sophisticated research techniques. In light of the existence of such a potential appliant pool, the quality and scientific merit of center grant applications could be expected to be high and the competition for awards quite rigorous.

BENEFICIAL CHARACTERISTICS OF RESEARCH CENTERS MECHANISM

NIH experience with specialized research centers suggests that they can provide a valuable means of focusing investigations on a given topic or disease.

For example, the National Heart, Lung and Blood Institute (NHLBI) has found that its hypertension centers, which focus on systemic hypertension, have helped to accelerate the process of generating new knowledge from fundamental and clinical research studies, which has direct and practical clinical applicability. NHLBI has also noted that the centers enable the Institute to respond quickly to new scientific questions.

A salient characteristic of research centers is their ability to bring diverse types of scientific expertise and approaches to bear on research problems and categorical diseases.

The science base in kidney and urologic disease, which has been developed primarily by individual investigators, could now be directed profitably to a multidisciplinary and possibly a multi-institutional approach to these diseases. In fact, research in kidney and urinary tract diseases could be expected to lend itself particularly well to cooperative efforts, since there has already been a long-term successful commitment to inter-institutional and inter-investigator projects focused on the issues of end-stage renal disease. In addition, the clinical problems for which these kidney and urologic diseases specialists are consulted often intersect, resulting in frequent collaborations.

In a research center environment, basic researchers and clinical investigators would be brought together to develop research programs focused on disease processes. This approach could help to bring advances in fundamental research investigations to bear on specific diseases and to open new areas of basic research. Investigators from several institutions might be brought together through a center to focus on a particular disease.

An example of the benefits of an interdisciplinary approach is the success of an NIADDK research project on polycystic kidney disease which spans several institutions and states. The result has been a considerable increase in understanding about a heritable disease process which accounts for nearly 10 percent of those patients entering end-stage renal disease. Because the chromosomal location of the defect has recently been discovered, it is now possible to tell which of the patients at risk carry the lethal gene prior to development of the disease. It thus now becomes possible to design studies addressing the prevention and/or treatment of renal cysts. In the past this disease could only be diagnosed after the kidneys were enlarged massively by cysts.

It is also important to note that centers can complement other existing NIH research support mechanisms such as regular research grants. They can provide an important new dimension and balance to an Institute's research portfolio in a given area of categorical disease research.

RECOMMENDATIONS OF PROFESSIONAL AND VOLUNTARY ORGANIZATIONS

The research centers concept is strongly supported by the academic research and clinical community in kidney and urologic diseases. For example, the Intersociety Council for Research of the Kidney and Urinary Tract has both endorsed and encouraged the establishment of such research centers. This Council is comprised of representatives from nine professional organizations representing most of the research and clinical communities actively engaged in research on and treatment of disorders of the kidney and urinary tract. According to thr Intersociety Council, intensification of kidney and urologic diseases research through a centers program could reduce by approximately 20 percent the number of patients entering the Federal End-Stage Renal Disease Program or requiring therapies for benign prostatic hyperplasia, at an estimated savings of $1 billion annually.

The National Kidney Foundation and its 50 regional affiliates are also very supportive of a research centers initiative and have designed a health promotion and education program that would complement the research aspects of a NIADDK kidney and urologic diseases research centers program. The Foundation's professional and public education program would provide a demonstration component that would be underwritten entirely by the Foundation and would cover the entire United States.

RECENT LEGISLATION RELATED TO CENTERS CONCEPT

In evaluating the centers concept, NIH recognized that Public Law 99-158, the Health Research Extension Act of 1985, gives the NIADDK the authority to "provide for the development and substantial expansion of centers for research in kidney and urological diseases." The centers proposal would be consistent with this new authorization.

CONCLUSION

The NIH has evaluated the proposal to establish up to six kidney and urologic diseases research centers. The concept would involve establishing research centers in: renal hypertension; diabetic nephropathy; obstructive, genetic or heritable diseases of the urologic system or kidney; nutrition in the management of kidney diseases; immunologic renal diseases; and renal cell injury. The goal of such a centers program would be the reduction of the major causes of kidney and urologic diseases by the early 1990s. The proposed program would focus on end-stage renal disease and benign prostatic hyperplasia.

In evaluating the proposed centers concept, the NIH considered a number of factors:

- o The health problems in ESRD and BPH are enormous, and current treatment approaches are only palliative.
- o Research opportunities are exciting and promising, however; and talented researchers have evidenced interest in pursuing recent research leads through a centers program that could be expected to foster competitive, meritorious research grant applications.

- Research needs and opportunities exist in each of the six research areas in which centers have been proposed.

- The specialized research centers mechanism offers unique opportunities for multidisciplinary and interdisciplinary research, as has been demonstrated by existing NIH centers programs.

- The kidney and urologic diseases research centers concept has been strongly endorsed by professional and lay groups in these fields, and is consistent with recently enacted NIH authorizing legislation.

In light of these considerations, there is sufficient reason to believe that the proposed research centers program is scientifically feasible and that it would contribute positively to advances in research knowledge and therapeutic approaches relative to ESRD and BPH. The NIH is therefore supportive of the concept of kidney and urologic diseases research centers, if additional resources were to be made available for this purpose.

Manpower Analysis

The House Appropriations Committee, in its report on the FY 1986 appropriations bill for the Department of Health and Human Services (page 98 of Report No. 99-289, dated September 26, 1985), requested an analysis of the manpower needs of the Social Security Administration. In this section of the budget document we will respond to that request. Since SSA has a workload-driven administrative budget, we relate workloads, which establish workyear needs, to employment. First, we will cover actual experience in FY 1985, and then explain the basis for our projections of the relationship between the work to be done and the workyears requested to do this work in FY 1986 and FY 1987.

FY 1985 Experience

The following tables compare SSA's experience in FY 1984 and FY 1985 with regard to beneficiaries, and selected workloads, pending levels, and processing times.

Beneficiaries in Payment Status

	FY 1984	FY 1985	Percent Change
OASI.....................	32,303,000	32,740,000	+1.4%
DI.......................	3,813,000	3,830,000	+.5%
SSI......................	3,923,000	4,065,000	+3.6%

Processed Workloads

	FY 1984	FY 1985	Percent Change
OASI claims..............	3,092,100	3,228,800	+4.4%
DI claims................	1,268,500	1,243,300	-2.0%
SSI claims...............	1,226,300	1,229,000	+.1%
Total.................	5,588,900	5,701,100	+2.0%
Appeal actions...........	1,167,200	1,090,800	-6.6%
Representative payee activity................	3,081,300	3,814,200	+23.8%
SSI redeterminations....	3,123,700	2,572,400	-17.6%
Annual earnings items...	193,653,200	214,569,300	+10.8%

Workloads Pending--End of Fiscal Year

	FY 1984	FY 1985	Percent Change
Field Offices			
OASI claims	151,400	155,400	+2.6%
DI claims	260,000	233,400	-10.2%
SSI aged claims	12,500	6,100	-51.2%
SSI blind and disabled claims	169,000	217,500	+28.7%
OASDI and SSI overpayments	122,400	86,000	-29.7%
Program Service Centers			
OASI claims	91,800	85,600	-6.8%
Overpayments	54,600	30,600	-44.0%
Office of Disability Operations			
DI claims	48,500	35,600	-26.6%
Office of Central Records Operations			
Certified wage records for OASI and DI claims	85,800	58,400	-31.9%
Office of Hearings and Appeals			
Hearings	107,800	107,600	-0.2%

Processing Time--Mean Days; Last Quarter of Fiscal Year

	FY 1984	FY 1985	Percent Change
OASI claims	23.4	21.4	-8.5%
DI claims	70.7	66.0	-6.6%
SSI aged claims	16.3	10.8	-33.7%
SSI blind and disabled claims	71.4	57.7	-19.2%
Hearings (mean shown for month of September	172	154	-10.5%

The preceding tables show that the OASI, DI and SSI beneficiary populations continued to rise in FY 1985 from the FY 1984 level, as did certain workloads (e.g., OASI, SSI claims, representative payee activity), while other workloads declined in FY 1985 (e.g., DI claims and appeals processed). Also the tables show that in FY 1985 SSA reduced significantly the numbers of workloads pending (backlogs) in all of SSA's workload processing components; and, by the September 1985 quarter had improved claims and hearings processing times by at least 6.6 percent and as much as 33.7 percent over the September 1984 quarter. The notable exceptions to this statement are the increases in OASI and SSI blind and disabled claims pending in the field offices, which were due, in part, to an increasing level of receipts during FY 1985. However, the overall mean processing time for claims declined during FY 1985.

Other evidence of improvements in SSA's service to the public which were achieved in FY 1985 follows:

- SSA completed the Automatic Earnings Reappraisal Operation (AERO) for 1982 and 1983 earnings, which adjusts benefit payment amounts for recent earnings, and continued to make major advances in improving the timeliness and degree of automation. The 1983 AERO was completed 5 months earlier than prior AERO's which means that beneficiaries were able to receive increases in their checks 5 months earlier.

- SSA processed the bulk of the 190 million 1984 annual wage reports 2 months earlier than the prior year's processing time.

- We decreased the time required to effectuate court orders from 179.7 days on the average in April 1985 to 99 days. Also we processed 90 percent of new court cases within 42 days, with an average processing time of 31 days. In FY 1984, less than 20 percent of the cases were processed within 42 days, and the average processing time was 60 days.

- We modified the underpayment review process to accelerate processing of these cases and improve payment quality.

A report issued by the General Accounting Office (GAO) in January 1986 offers corroborating evidence that SSA is providing good service in spite of employment reductions. The report shows that the quality of SSA's service to the public was generally rated as high by the public we serve. This conclusion was based on a nationwide survey of 1,680 SSA clients in November and December 1984. They were asked to comment on their recent contacts with SSA by telephone, visit or correspondence, with regard to such issues as courtesy, waiting times, privacy and clarity of explanations. The survey found that overall, in spite of the increasingly complex programs which SSA administers, 87 percent of those surveyed found SSA service to be good to very good, and more than 50 percent rated SSA's service better than that received from other government agencies. In addition to SSA's objective measures such as accuracy and processing time, the public's perception of the quality of our service is an important indicator of how well we are doing our job.

Nevertheless, SSA management is concerned about improving the accuracy of information provided the public by SSA employees, and we will take steps to improve its accuracy. This is less a matter of manpower than of training.

SSA was able to process its workloads in FY 1985, reduce pendings and processing times, and improve service to the public with fewer workyears, primarily through management initiatives to improve work processes and increase automation. SSA achieved a 2.3 percent increase in productivity in FY 1985, which is consistent with the Agency's performance over time. During the 10-year period FY 1976 - FY 1985, SSA achieved a 30 percent increase in productivity, or an average of 3 percent per year.

SSA's productivity improvements resulted primarily from efforts to increase Agency efficiency through automation and through procedural changes designed to streamline or simplify the manner in which work is handled by SSA employees. Some examples of these initiatives and the workyears saved in FY 1985 (from the 1984 base) are:

Initiatives	FY 1985/FY 1984 Workyear Savings
1. Projects under the Commissioner's Workload Management Initiative,.............. including:	-1,178
o Improving the automation rate for AERO (Automatic Earnings Reappraisal Operation) which recalculates benefit amounts using the latest posted earnings	
o Changes in the SSI redetermination selection process to target resources on areas of highest vulnerability	
o Simplified documentation practices in the OASDI and SSI programs	
2. Increase in the amount of annual wage reports received on magnetic media......................	-115
3. Replacement of card readers with scanning devices for case control and folder location in the Office of Central Operations...	-130
4. Improvements to the Claims Automated Processing System (CAPS) to include cases formerly excluded from automated processing.........................	-76

Initiatives	FY 1985/FY 1984 Workyear Savings
5. Net, other management, procedural and systems changes............................	-37
Total Savings, FY 1985/FY 1984...	-1,536

In addition, because of two major areas where workloads were less than budgeted in FY 1985, SSA was able to reduce significantly its level of overtime. The table below shows actual Limitation on Administrative Expenses (LAE) overtime worked by SSA in FY 1984 and FY 1985 and the budgeted level for FY 1985:

	FY 1984	FY 1985		
	Actual	Operating Budget Estimate	Actual	Difference
Overtime Workyears........	3,990	3,732	2,317	-1,415
Percent of total workyears................	4.7%	4.5%	2.8%	-1.7%

The major reasons for the decrease in overtime were:

- o Budgeted inquiries related to the first year of implementation of the taxation of benefits provision of the Social Security Amendments of 1983 did not materialize as expected. The budget included 1,649 workyears for implementation of taxation of benefits; SSA expended 618 workyears on this initiative in FY 1985.
- o The FY 1985 budget assumed that the moratorium on continuing disability reviews (CDR's) would be lifted on April 1, 1985. This did not occur until after the final regulations on the new medical improvement standard were published in December 1985. Thus the 216,000 budgeted CDR's were not processed in FY 1985.

The following table shows changes in SSA's employment, full-time equivalents (FTE's) and workyears in FY 1985 from the FY 1984 level:

	FY 1984	FY 1985	Change
Limitation on Administrative Expenses (LAE) Account			
FTE's.............................	79,951	77,741	-2,210
Total workyears....................	86,189	82,131	-4,058
Full-time permanent (FTP) employment, end of fiscal year.............................	72,490	71,048	-1,442

Even though SSA's employment, FTE's and workyears declined in FY 1985 from the FY 1984 levels, SSA had sufficient manpower resources to meet its needs. With fewer employees and less overtime in FY 1985, SSA served growing beneficiary populations and processed increasing workloads in some categories, while at the same time reducing pending workloads and improving processing times.

Budget Plan for FY 1986 and FY 1987

SSA's estimates of its workyear requirements for FY 1986 and FY 1987 are built upon the agency's experience in FY 1985. Given this "base year" experience, which covers numerous SSA workloads and the time it takes to process each unit of work, projections of future workyear needs take into account how this experience will change in terms of:

--The volume of work the Agency will have to process.

--Various factors which will affect the time it takes to process its work, including plans to automate and streamline operations and including anticipated changes in the workload/employment balance.

--Manpower for functions not directly associated with but needed to support "on the line" workload processing.

The derivation of SSA's overall LAE workyear estimates for FY 1986 and FY 1987 is summarized in the following table. As indicated, SSA's revised budget estimates for FY 1986 reflect a bottom-line reduction of 1,575 workyears needed to live within the constraints established by the Balanced Budget and Emergency Deficit Control Act of 1985, more commonly known as Gramm-Rudman-Hollings.

It should be noted that the total workyear requirements for FY 1986--80,558 workyears--are based on the latest beneficiary and workload projections developed by SSA's actuaries and statisticians. This estimate of requirements is nearly 670 workyears below the level projected in the FY 1986 President's budget. Some of the factors that account for this decrease are a reduction in workyears required for administering the new taxation of benefits provision of the Social Security Amendments of 1983, and a one-quarter delay in the resumption of continuing disability review processing.

In addition, reductions under Gramm-Rudman-Hollings will be achieved, in part, by reducing 1,575 workyears of overtime and nonceiling employment, not by reducing FTE's.

	SSA Workyears	
	FY 1986	FY 1987
Prior Year Requirements	82,131	80,588
Changes:		
Workload Volumes	+2,946	+1,307
Automation and Streamlining	-2,206	-2,046
Workload/Employment Balance	-966	-1,315
Operations Support Functions	-1,317	+46
Total Requirements	80,588	78,580
Gramm-Rudman-Hollings Reductions	-1,575	--
Budget Estimates	79,013	78,580

Beneficiary and workload projections developed by SSA's actuaries and statisticians are the key indicators which influence the amount of work SSA can expect. Based on actuarial and statistical projections, SSA has developed estimates of the workloads it expects to process in FY 1986 and FY 1987. Comparisons of those estimates to FY 1985 actual experience for beneficiaries in current payment status and for SSA's major processed workloads are provided below:

	FY 1985 Actual	FY 1986 Estimate	FY 1987 Estimate
Beneficiaries in Payment Status			
OASI	32,740,000	33,323,000	33,980,000
DI	3,830,000	3,927,000	3,974,000
SSI	4,065,000	4,153,000	4,264,000
Processed Workloads			
OASI Claims	3,228,840	3,294,100	3,336,900
DI Claims	1,243,300	1,313,300	1,404,200
SSI Claims	1,229,000	1,380,100	1,396,000
Rereviewed Claims	--	185,000	--
Total	5,701,100	6,172,500	6,137,100
Appeal Actions	1,090,800	1,168,930	1,241,130
Representative Payee Activity	3,814,200	4,019,600	4,593,100
SSI Redeterminations	2,572,400	2,555,600	2,659,200
Annual Earning Items	214,569,300	218,708,000	225,379,000

The above workload estimates reflect the following trends and initiatives:

-- Normal year-to-year growth in beneficiaries and in claims, due to demographic factors.

-- Resumption of CDR processing in the second quarter of FY 1986, following a moratorium in effect since April 1984.

-- Hearing workloads which reflect CDR resumption. Hearings occur at the tail end of the appellate process and are now expected to increase through FY 1986 and FY 1987.

-- An increase in representative payee accounting due to implementation of the Jordan court decision which calls for annual accounting for all payees.

In comparison to FY 1985, there is an aggregate increase in the volume of work SSA anticipates, which amounts to 3.6 percent in FY 1986 and 1.6 percent in FY 1987. These increases are the net effect of many pluses and minuses which take into consideration:

-- The workload count changes reflected in the table above.

-- Changes which may occur in the internal composition of a particular workload. For example, while both workers and dependents are included in RSI claims counts, dependent claims take less time.

-- The fact that certain workloads, such as RSI claims, are less time consuming than others, such as disability claims.

In the absence of any other changes, the aggregate increase in workload volumes increases SSA resource requirements by 2,946 workyears in FY 1986 and by another 1,307 workyears in FY 1987. As indicated earlier, however, SSA's analysis of its FY 1986 - FY 1987 workyear requirements takes into account other factors which affect the Agency's workyear needs:

-- Anticipated changes related to management, procedural and systems improvements (i.e., automation and streamlining), discussed in more detail later, reduce SSA needs by 2,206 workyears in FY 1986 and by another 2,046 workyears in FY 1987.

-- Anticipated improvements in the balance between the amount of work on hand and the number of employees in place to process this work decrease resource requirements by 966 workyears in FY 1986 and by 1,315 workyears in FY 1987. Unlike the above factors which are related to specific plans, this change is related to experience in FY 1984 and in FY 1985, when the workload/employment balance fell below budgeted levels, mainly because work did not materialize as a result of the moratorium on CDR processing even though SSA had in place the complement of employees needed to handle this workload. Now that CDR processing has resumed, SSA expects the balance between workloads and employment to return to normal levels during FY 1986 and FY 1987, thus reducing workyear requirements in comparison to FY 1985.

-- Changes in workyear requirements for functions such as case control and filing, training and supervision (i.e., operation support functions) occur as a natural by-product of reductions in the workyears actually needed "on the line" to process SSA workloads. In addition, SSA plans to improve the ratio between workyears for these functions and for direct processing functions. This results in a reduction of 1,317 workyears in FY 1986, which carries virtually unchanged into FY 1987.

As indicated above, SSA estimates that savings of 2,206 workyears in FY 1986 over FY 1985 and 2,046 workyears in FY 1987 over FY 1986 will result from management, procedural and systems improvements. Major initiatives for FY 1986 and FY 1987 are listed below:

	Workyear Savings	
	FY 1986/FY 1985 Savings	FY 1987/FY 1986 Additional Savings
1. Projects in the Commissioner's Workload Management Initiative, including:	-575	-292
o Elimination or modification of unproductive alerts and diaries in the field offices and program service centers		
o Mid-year follow-up with working beneficiaries for reestimate of annual earnings to prevent overpayments.		
o Processing all OASI overpayment waiver requests in the field offices, based on information in the Payment History Update System and the Master Beneficiary Record, instead of sending them to the processing centers for a folder review.		
2. Field Office Systems Enhancement--development of an automated title II claims taking process, which will include immediate data entry and edit and system generation of application documents	(70)	-439
3. Expansion of district office final authorization (DOFA) of initial claims to include cases currently referred to the program service centers for final authorization	-0-	-329
4. Increase in the amount of annual wage reports received on magnetic media	-135	-67

	Workyear Savings	
	FY 1986/FY 1985 Savings	FY 1987/FY 1986 Additional Savings
5. Improvements and modifications to the claims automated processing system (CAPS) to include cases formerly excluded from automated processing (e.g., ALJ reversals)......................	-226	-24
6. Third party query system--automation of the procedure used by field offices to furnish benefit payment information to State welfare agencies........................	-261	-0-
7. Automated process to offset the initial retroactive title II benefit for periods in which the claimant received SSI benefits...........	-137	-146
8. Change-of-address processing modifications which will eliminate most of the RSDI and SSI nonreceipt-of-check workload caused by recent changes in address..............	-0-	-164
9. New short-form SSI redetermination questionnaire for field office use--form will be mailed or will result in less time-consuming interviews..	-308	-0-
10. FTE reductions from streamlining staff functions.................	-184	-420
11. Net, miscellaneous additional improvements.....................	-450	-165
Total Workyears Saved.....	-2,206	-2,046

Mix of SSA Workyears in FY 1986 and FY 1987

SSA will continue to rely on a mix of FTE's, nonceiling employment and overtime to achieve its overall workyear needs. The following table, which includes bottom-line FY 1986 Gramm-Rudman-Hollings reductions, shows how SSA plans to achieve its workyear needs for the LAE account in FY 1986 and FY 1987. These plans are compared to FY 1985 actual experience.

	LAE Workyears		
	FY 1985 Actual	FY 1986 Estimate	FY 1987 Estimate
FTE's	77,741	76,169	73,270
Nonceiling	2,073	1,069	1,786
Overtime	2,317	1,775	3,524
Total	82,131	79,013	78,580
Overtime as percent of total workyears	2.8%	2.3%	4.5%

Consistent with the reduction in overall workyear requirements, SSA's plans reflect a continued decrease in FTE's in FY 1986 and FY 1987. We do not expect that a deterioration in SSA's service will occur with the level of FTE's currently estimated. SSA will be reporting quarterly to the Congress on a number of key indicators of public service, such as payment accuracy and regional and national processing times for key workloads. Over time, these reports will make it possible to objectively determine whether any decline in service takes place.

Overtime and nonceiling (principally summer youth employment) workyears have been reduced in FY 1986 as a result of reductions in available funds due to Gramm-Rudman-Hollings. These reductions will not require reductions-in-force or furlough of Federal employees.

SSA's budget plan for FY 1987, which was developed before Gramm-Rudman-Hollings reductions were mandated in FY 1986, restores nonceiling and overtime workyears to higher levels. As in FY 1985, if workloads fail to materialize as budgeted, SSA will reduce the level of overtime worked.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health

National Library of Medicine

PRESERVATION OF THE BIOMEDICAL LITERATURE:

A Plan for the National Library of Medicine

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February 1986

PRESERVATION OF THE BIOMEDICAL LITERATURE:

A Plan for the National Library of Medicine

In its report on the Fiscal Year 1986 budget for the Department of Health and Human Services, the Committee on Appropriations stated:

> "The Committee is particularly concerned about the preservation of the Library's collection, and requests a report on this subject, including funding requirements, prior to next year's hearings." (House Report No. 99-289, page 79)

In response to this request, the following report, developed by the National Library of Medicine beginning in August of 1984 as a first step toward developing a formal preservation program, is submitted by the National Institutes of Health of the Department of Health and Human Services.

The Library has begun to implement the recommendations contained in the report. A Preservation Section is being established and recruitment is underway for its chief. The statement of work has been developed for microfilming services to be performed on-site by a contractor. It is expected that such preservation microfilming will begin in the latter part of FY 1986.

PRESERVATION OF THE BIOMEDICAL LITERATURE:

A Plan for the National Library of Medicine

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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I. EXECUTIVE SUMMARY

Introduction

The National Library of Medicine Act of 1956 (P. L. 84-941) established the Library and charged it "to acquire and preserve books, periodicals, prints, films, recordings, and other library materials pertinent to medicine." In the years since the establishment of the Library, significant effort has been devoted to carrying out NLM's preservation responsibilities. NLM currently devotes 11 FTEs and nearly one million dollars annually to preservation activities. The Library has archival copies of many significant items in its collection; a storage plan which accommodates projected growth of the collection through the year 2000; generally favorable conditions for processing, storing, and using library materials; and an official NLM Board of Regents' policy governing NLM's preservation activities.

Despite these achievements, NLM must take a more comprehensive approach to preservation of the biomedical literature if it is to carry out its statutory mandate successfully. Recognizing the need for greater focus on NLM's preservation responsibility, in 1983 Library Operations (LO) senior staff included the development and implementation of a program for the preservation of the biomedical literature as one of the four broad objectives in the LO strategic plan for 1984-88. As a first step toward developing a formal preservation program, the Associate Director, LO appointed a senior Preservation Planning Team on August 29, 1984.

With assistance from over thirty staff members throughout the Library, the Preservation Team has analyzed the state of the NLM collection, its environment, and use, and available options for preservation. This report documents the Team's findings and presents a recommended plan of action for the Library.

Condition of the Collection

The physical condition of library materials is a function of three principal factors: (1) the substances used in their manufacture and how these substances change with age; (2) the environmental conditions in which the materials are housed; and (3) how, and how often, the materials are handled. Most of the 3.3 million items presently in the NLM collection, like most of the materials in other research libraries, are composed of substances that predispose them toward rapid deterioration. The degree of deterioration varies from library to library, however, depending on the relative age and quality of the materials included in the collection and the storage and use conditions to which the materials have been subjected.

Random samples of the various elements in the NLM collection revealed that approximately 8.8% or an estimated 113,000 volumes in the paper-based collections are brittle. By taking action immediately, NLM can ensure preservation of the content of the endangered volumes and also extend the life of the remainder of the collection. Delays may lead to the loss of already embrittled materials and an increase in the number of brittle items requiring very expensive preservation techniques.

Physical Facilities And Environment

There are five environmental factors which affect the longevity of library materials: temperature and relative humidity, atmospheric pollutants, light, mold, insects and rodents. The NLM Library building was surveyed for all factors.

Although some problems were discovered, in general the environmental conditions in the Library are good, and they probably can be improved without great expense. The construction of the Library, with relatively few windows and three floors below ground, makes it easier to maintain appropriate temperatures for the collection and to minimize the amount of ultra-violet radiation. Concern for the preservation of the collection is evident in the design of the building and in its heating and air-conditioning system.

Collection Use and Maintenance

The amount and nature of physical processing, handling and use of Library materials by staff and patrons have an effect (either positive or negative) on the life of those materials. The mission of any library is almost inevitably in conflict with preservation of its contents, for materials are acquired, organized and stored primarily to be used, and use necessarily takes a toll on condition. Therefore, there will always be a tension and compromise between the need to preserve material and to make them readily available to the Library's users.

The results of the survey of the physcial condition of items in the NLM collection indicate that current processing and use practices are not having a serious negative effect on the Library's materials. This does not mean, however, that there is no room for improvement in the way NLM's collection is handled by staff and users. The process of observing, documenting and discussing the use and processing practices that can affect the Library's collections has already caused staff members to be more preservation conscious and alert to potentially damaging handling policies and techniques. Some physical damage is unavoidable in a service organization where use is expected and encouraged, but steps can be taken to reduce even further damage during processing and after the materials are in the users' hands.

Current State of Preservation Technology

In the broadest sense, any activity which extends the life of library materials is a preservation technique. This is why the enhancement of the environment in which materials are stored and improvements in the way materials are handled are important to preservation programs. Using a narrower interpretation, however, a preservation technique is something which improves the intrinsic durability of an item or creates a copy of it in a more durable medium. Relatively few such techniques exist, particularly for mass preservation of the post-1850 paper-based materials most at risk. Fortunately, recent expansion of interest in preservation among research libraries has sparked research in mass preservation techniques. Although currently available options are still very limited in number, there is promise of better things to come.

The major techniques that are currently available, or are the subject of research activity, are: mass deacidification; strengthening of brittle paper; mass disk storage; microfilming; film-to-film transfer; a variety of manual methods for rare books, manuscripts, and prints and photographs; and the acquisition of materials in archival formats.

When it becomes generally available, presumably in two to three years, mass deacidification will probably be the cheapest alternative for preservation of paper-based materials. While it is not useful for materials that are already brittle, it is a suitable technique for the bulk of NLM's paper-based collections. The newer materials are at the time they are deacidified, the more they can benefit from the process.

Mass disk storage has exceptional use characteristics, including random access, simultaneous use by multiple users, and the ability to be linked directly to automated bibliographic records. The preservation characteristics of disks are not fully understood, however, and require further research. The results of such research are needed before accurate total cost estimates for preservation on disk can be developed.

Of the preservation techniques suitable for the mass of NLM's printed collections, only microfilming is available to NLM today. Microfilm is very space efficient if the original is not retained after filming, but it is also unwieldy to use. This may not be a serious problem for older materials that receive relatively infrequent use.

Other Factors Affecting NLM's Preservation Program

NLM's preservation program must take into account a number of external factors affecting the U.S. information and biomedical communities. These include publishing trends; developments in the concept of intellectual property rights; changes in the ways health professionals acquire and use information; and the emergence of preservation as a critical concern in research libraries, which in turn has led to increased emphasis on cooperative library activities and significant developments in preservation technology.

Recommended Strategies for Preservation at NLM

An examination of the current condition of the NLM collection, the environment in which it is stored, the way its materials are processed and used, and the present level of preservation activity has revealed a preservation problem that can be solved if NLM takes immediate action to establish a comprehensive preservation program. In many respects, NLM is in a much better position than other U.S. research libraries which have such huge numbers of brittle materials that there is almost no possibility of saving them at all. Due to the relatively good condition of the NLM collection and its manageable size, NLM has the opportunity to fulfill its mandate to preserve the biomedical literature.

After careful evaluation of available options, the Preservation Planning Team recommends that NLM take the following actions to create a preservation program capable of ensuring the long-term availability of the scholarly record for biomedicine.

A. MODIFY THE NLM BOARD OF REGENTS POLICY ON PRESERVATION

The NLM Board of Regents' policy on preservation of the collection should be modified to link NLM's preservation program more explicitly to its collection development guidelines, to clarify the Library's responsibility for the preservation of the content as opposed to the format of the biomedical literature, and to define NLM's role in assisting the preservation of significant biomedical literature held by other U.S. libraries.

The Preservation Planning Team has prepared a draft policy statement for consideration by the Director, NLM and the Board of Regents. The full text of this draft statement is included in Appendix 5 of the report.

B. ESTABLISH A NEW ORGANIZATIONAL UNIT TO DIRECT NLM'S PRESERVATION PROGRAM

NLM's existing preservation organization, while appropriate for the level of preservation activity currently underway, is inadequate to handle the expansion of preservation functions that the Library must undertake to ensure the preservation of the scholarly biomedical literature. The Preservation Planning Team recommends that a Preservation Section be established within the Reference Services Division to provide an operational focus for NLM's preservation activities and assume direct responsibility for many of them. Given present constraints, the new Section must be developed by reallocating existing staff and positions. It should also continue NLM's current practice of contracting out most of the actual physical preservation or copying of materials to archival formats.

C. EXPAND THE LEVEL OF PRESERVATION ACTIVITY AT NLM

Because NLM has the largest collection of biomedical literature in the world, preservation of the materials held by the Library represents a significant step toward preservation of the entire scholarly record in the field of medicine and health. With the completion of this comprehensive study of internal and external factors affecting preservation of the NLM collection and the adoption of a preservation policy, the Library should expand its preservation program to achieve by the year 2005 the goal of a preservation copy for every item in the NLM collection that falls within the core biomedical literature that NLM collects comprehensively or within the subjects related to medicine and health that NLM collects at the research level. NLM should take the following specific steps toward this goal.

Mass Deacidification

Beginning in FY 1988, NLM should deacidify 100,000 volumes annually, including all incoming print materials that would benefit from this treatment and making up the remainder from items in the retrospective collection. Depending on the number of new materials acquired on acid-free paper or in non-print form each year, it will take 18-20 years to deacidify the entire retrospective collection that would benefit from this treatment, while also treating all appropriate incoming materials. The cost, depending on the mix of new and old materials, will range from $370,000 to $400,000 annually (in FY 1985 dollars) until all the retrospective collection has been treated. These cost figures are based on the use of an existing facility, and exclude any charges to defray the cost of facility construction.

To make certain that mass deacidification services at the required level are available to the Library by 1989, NLM should negotiate with LC for a firm commitment for NLM use of the mass deacidification facility at Frederick. If sufficient capacity cannot be made available at the LC facility, NLM should work with other research libraries and/or commercial companies to ensure the development of adequate deacidification service for the NLM collection.

Microfilming

Using contract support for preparation and an outside filmer, NLM should microfilm all brittle monographs and serial volumes in subjects it collects at the comprehensive or research level during FY 1986 - 89. Expenditures for this program should be phased as follows: $600,000 in FY 1986; $1 million per year in FY 1987 through FY 1989. The Library should assume that microfilming any post-1906 embrittled materials in order to preserve them represents a "fair use" of the materials.

Treatment of brittle pamphlets and theses should be deferred pending resolution of the more immediate problem of how the Library is to provide bibliographic control for these items.

In 1988/89, NLM should reassess any further use of preservation microfilming based on the results of research in techniques for the preservation use of mass disk storage. Previously microfilmed images can be transferred to disk if this seems advisable at a later date.

Preservation of Special Historical Collections

NLM should allocate at least $200,000 per year to preservation of special collections for the five-year period from FY 1986 - FY 1990. In 1988/89, NLM should be in a position to estimate the level of funding required for continuing maintenance and treatment of new acquisitions for these special collections.

D. CONTINUE RESEARCH ON THE PRESERVATION CHARACTERISTICS OF OPTICAL DISKS

Because of the great potential of optical disk as a preservation medium, NLM should continue to contribute to the development of knowledge about the preservation characteristics of this technology. The prototype Electronic Document Storage and Retrieval (EDSR) system developed in the Lister Hill National Center for Biomedical Communications (LHNCBC) should be used as a laboratory test bed for relevant research projects. LHNCBC budget plans for the next few years includes appropriate funding for this activity. To ensure that the greatest amount of useful information is obtained in the shortest time frame, NLM's research efforts in optical disk technology should be closely coordinated with those of the Library of Congress, the National Archives, the National Bureau of Standards and other interested institutions.

E. ENCOURAGE PUBLICATION IN ARCHIVAL FORMATS

Publication of the scholarly literature on acid-free paper or in other archival formats will lessen the necessity for large-scale treatment of the prospective literature. To this end, NLM should launch a campaign to convince biomedical editors, societies, and publishers of the benefits of publication in archival formats. This campaign should involve a combination of direct appeals by NLM and cooperative efforts with other national libraries and library associations.

F. IMPROVE CONDITIONS FOR STORAGE AND USE OF THE NLM COLLECTION

Proper storage and handling of library materials will extend their life. An examination of storage and use conditions at NLM has revealed that in general NLM's collection is stored in a benign environment and is handled with reasonable care. Steps should be taken, however, to ensure that this generally favorable situation continues and that specific problems are corrected.

G. INITIATE AND PARTICIPATE IN COOPERATIVE PROGRAMS FOR THE PRESERVATION OF THE BIOMEDICAL LITERATURE

Although NLM's first priority is the preservation of its own collection of materials collected at the comprehensive and research levels, it also has an obligation to engage in cooperative activities which will ensure the preservation of materials pertinent to medicine held by other libraries and will contribute to a national preservation program. While the emerging national program provides an infrastructure in which to fit the preservation of the biomedical literature, it does not presently address coverage of the biomedical area. NLM must assume the responsibility for the development of a plan to fill this gap.

H. RE-EVALUATE NLM'S PRESERVATION PROGRAM PERIODICALLY

Like other NLM programs, the preservation operation will be monitored through regular reporting mechanisms and the program review that accompanies budget preparation and approval. Given the new emphasis to be placed on preservation, however, NLM should also perform a broader review of progress toward the goal of preservation of the biomedical literature at approximately three-year intervals. During this review, NLM should reassess its preservation assumptions and strategies in light of the current and future information needs of the Library's users and developments in preservation technology.

II. INTRODUCTION

The National Library of Medicine Act of 1956 (P. L. 84-941) established the Library and charged it "to acquire and preserve books, periodicals, prints, films, recordings, and other library materials pertinent to medicine." The Act further authorized the Surgeon General to "Exchange, destroy, or otherwise dispose of any books, periodicals, films and other library materials not needed for the permanent use of the Library." Taken together these two clauses clearly give NLM a mandate to preserve the biomedical literature irrespective of its format and also provide the Library with the discretion to select among the materials in the collection those which should be permanently retained and preserved.

In the years since the establishment of the Library, significant efforts have been devoted to carrying out NLM's preservation responsibilities. Due in large part to the leadership of Albert Berkowitz, former Chief, Reference Services Division, the Library has archival copies of some of the most significant items in its collection; a storage plan which accommodates projected growth of the collection through the year 2000; generally favorable conditions and practices for processing, storing, and using library materials; and an official NLM Board of Regents' policy governing NLM's preservation activities. The text of this policy is as follows:

> In accordance with the terms of the NLM Act and the clearly expressed intent of Congress, the fundamental responsibility of the National Library of Medicine is to preserve permanently its collection of books, periodicals, and other library materials pertinent to medicine, without respect to the practices of other institutions.
>
> Means of preservation may include:
>
> A. Preservation of the original.
>
> B. The purchase of library materials in microform or other formats provided an examination of adequate samples affords satisfactory evidence that the film or other medium meets NLM standards for archival quality.
>
> C. Replication of material in the collection through microphotography, or other means as the Director may determine, using new methods made practicable by advancing technology.
>
> The Director will establish criteria to determine priority of selection for preservation. Items in the collection will be retained in the original form as long as they remain useful.
>
> The Library should continue to monitor the development of technologies which offer alternatives to microphotography for

the preservation of information and should participate in such research, development, testing, and evaluation.

Despite these important accomplishments, NLM must take a more comprehensive approach to preservation of the biomedical literature if it is to carry out its statutory mandate successfully. Like the collections of other research libraries, NLM's printed collections contain the seeds of their own destruction in the form of high-acid content paper which, over time, discolors, becomes embrittled, and finally disintegrates. In addition, the Library faces special problems related to the conservation and preservation of audiovisual programs, archival microfilms, and historical motion pictures and the History of Medicine Division's manuscripts, older printed works, prints and photographs. Preservation of the scholarly record is one of the most important challenges facing research libraries today, requiring significant expenditures of resources, the interest and involvement of all staff who process or use the collection, active cooperation among many institutions, and new organizational approaches.

In 1983, Library Operations (LO) senior staff developed a strategic plan for 1984-88 which includes as one of its four broad objectives:

> to develop and implement a program for the preservation of the biomedical literature.

As a first step toward developing a formal preservation program, the Associate Director for Library Operations appointed a senior Preservation Planning Team on August 29, 1984.

The Team was given the following charge:

1. Assess the current physical state of the collection.
2. Assess the conditions under which the collection is used, processed, and stored.
3. Examine current preservation activities in all LO components.
4. Identify and evaluate available preservation techniques.
5. Identify current and potential cooperative preservation activities.
6. Develop a plan for the preservation of the NLM collection which includes recommendations for:
    a. organizational responsibility for NLM preservation activities
    b. general guidelines for selecting items to be preserved and assigning preservation priorities
    c. methods for preservation of various parts of the

collection including cost data and suggested schedules

d. necessary changes to environmental conditions and processing and use practices

e. cooperative activities NLM should participate in or initiate

The planning process used for this project was modeled on a self-study procedure developed by the Office of Management Studies (OMS) of the Association for Research Libraries (ARL) and described in Preservation Planning Program: An Assisted Self-Study Manual for Libraries. NLM contracted with OMS for assistance in developing the plan and the results of NLM's effort will be shared with the ARL and biomedical library communities. Ms. Jutta Reed-Scott served as principal OMS consultant to NLM for the project.

The planning process consisted of three phases. During the first phase, the Preservation Planning Team reviewed basic preservation issues and assembled background information about the library. This material was included in a background paper entitled "Preservation at the National Library of Medicine" (Appendix 1), completed in November, 1984. The background paper provided a context for the examination of the Library's preservation needs, established a series of Task Forces (including the identification of participants and specific charges), and outlined a schedule for the planning process.

The second phase involved seven Task Forces gathering and analyzing data and developing recommendations in several specific areas affecting preservation. Task Forces were assigned to assess the physical condition of the collection, environmental conditions affecting the collection, processing and use practices, preservation techniques, organizational responsibility for preservation, cooperative preservation activities, and the adequacy of the current NLM disaster recovery plan. A list of all Task Force members appears in Appendix 2.

In the third and final phase, the Preservation Planning Team has studied information assembled by the Task Forces, weighed alternative approaches, and developed this report with its recommended plan of action.

III. CONDITION OF THE COLLECTION

The physical condition of library materials is a function of three principal factors: (1) the substances used in their manufacture and how these substances change with age; (2) the environmental conditions in which the materials are housed; and (3) how, and how often, the materials are handled. The majority of library materials in existence today are printed works that were published after 1850. Mass produced, alum-rosin sized ground wood paper entered commerce around 1850 and most books and journals published since 1870 have been printed on it. Although there are varying degrees of quality in this paper, all of it is less strong than paper with cotton fibers because of the short fibers in wood pulp, and all is destined to disintegrate because of its relatively high-acid content. The condition of high-acid content paper begins deteriorating rapidly as soon as it is produced. The rate of deterioration slows as the paper becomes progressively embrittled. Although acidic paper may be the principal cause of the deterioration of library collections, other substances, such as nitrate-based film, also present significant preservation problems.

Most of the materials presently in the NLM collection, like most of the materials in other research libraries, are composed of substances that predispose them toward rapid deterioration. The degree of deterioration varies from library to library, however, depending on the relative age and quality of the materials included in the collection and the storage and use conditions to which the materials have been subjected. Since no reliable conclusions about the state of the NLM collection could be drawn from studies of other collections, an obvious prerequisite to the development of a preservation plan for the NLM collection was the gathering and analysis of data on the present state of NLM's library materials. Consequently one of the principal activities of the planning process was a survey of the condition of the NLM collection.

The NLM collection today stands at 3.3 million items in a variety of formats including books, journals, audiovisual materials, microfilm, manuscripts and prints and photographs. An annual literature budget of about $2.2 million supports the acquisition of approximately 16,000 books, 1,000 audiovisuals, 23,000 serial titles, 33,000 manuscript items, and 450 prints and photographs each year. The Library collects materials comprehensively in all major areas of the health sciences and to a lesser degree in related areas such as chemistry, physics, botany and zoology. (For a discussion of the historical development of the NLM collection see Appendix 1, p. 7.)

Survey Methodology

As a first step to sampling the condition of the collection, the following discrete groups of material were identified:

- Printed materials published prior to 1801 (40,000 volumes)
- Monographs published between 1801 and 1870 (40,000 vols.)

- Monographs published from 1871 to date (465,000 vols.)
- Serials published from 1801 to 1870 (20,000 vols.)
- Serials published from 1871 to 1969 and located on the B-3 stack level (371,000 vols.)
- Serials published from 1969 to date and located on the B-1 stack level (278,000 vols.)
- Serials published from 1871 to date and located on the B-2 stack level (91,000 vols.)
- Pamphlets located in HMD and on the B-2 stack level (172,000 in 7,249 boxes or bound volumes)
- Theses located in HMD (282,000 in 6,408 boxes or bound volumes)

° Modern unbound manuscripts	(1,206,000 items in 2,700 boxes)
° Bound manuscripts	(1,000 vols.)
° Videocassettes	(5,900)
° Audiocassettes	(9,000)
° 16mm Films	(2,300)
° Filmstrips	(844)
° Slides	(230,000 in 3,000 carousels)
° Historical Film Collection	(2,000 reels)
° Fine prints and photographs	(75,000)
° Microfilm	(34,000 reels)
° Microfiche	(122,000 items)

The decision was made not to survey the condition of the following parts of the collection for the reasons described below:

- Printed materials published prior to 1801 (40,000 volumes).
- Bound manuscripts (1,000 volumes).
- Historical Film Collection (2,000 reels).

These collections have already been examined comprehensively, and programs are underway to preserve them. In general, the condition of the pre-1801 printed collection is good. Many bound manuscripts require rebinding, and this process is underway. Most items in the historical film collection must be transferred to new film stock in order to preserve them.

- Fine Prints and Photographs (75,000 items)
- Microfilm (34,000 reels)
- Microfiche (122,000 items)

There is insufficient in-house expertise to assess the deterioration of these three groups of material. Library Operations is taking steps to have these collections assessed by outside experts.

All other elements of the collection were sampled during the course of this preservation study.

Sample Selection

After consulting several standard sources on statistics and sampling, the Task Force on the Physical Condition of the Collection decided to use the procedures described by M. Drott (1). As high a level of confidence and as small a range of tolerance as possible were desired, given the available resources and established time frame.
Taking all factors into consideration, it was agreed that a level of confidence of 95% with a tolerance of ± 5% would be both acceptable and manageable. This resulted in sample sizes of up to 384 items in each discrete collection.

For paper-based materials, neither the automated bibliographic files nor the manual shelf list of the NLM collection provide comprehensive coverage at the item level, so that every physical piece in each discrete location could be represented. Since each piece had to have an equal chance of being selected in the samples and the bibliographic files could not assure this, sampling of the paper-based materials was done directly from the shelves.

The paper-based collection is housed on ranges, or rows of stacks. Each range is comprised of from eight to twelve three-foot sections; and each section is comprised of six to seven shelves. Each of the ranges in all of the collections to be sampled was given a unique number. These numbers were later correlated to a simple list of sequential numbers to facilitate look-up in a random number table.

Selection of each sampled piece in each discrete collection followed a strict four-step process as follows:

From a table of random numbers, select:

1. Number corresponding to range number

2. Number corresponding to a section within the range
3. Number corresponding to a shelf within the section
4. Number corresponding to the book count from left to right on the shelf

To speed the process and to eliminate reference to random number tables while actually in the stacks, work sheets were made up in advance so that staff collecting the sample could put their worksheets in range order and move through the collections in one sweep.

For most of the audiovisual media, listings from AVLINE by media type could be used, rather than direct shelf sampling, since each physical audiovisual piece had an equal opportunity of being selected from the listings. Random number tables were used to select the samples from the listings. Audiocassettes were sampled by a method similar to that used for print materials, with cabinets and drawers substituting for ranges and shelves, in the selection of the sample.

Information Collected

For each item sampled, the call number (including volume number and year) and a short title were recorded. For paper-based materials, two major aspects of physical condition were recorded:

(1) Overall condition of the binding and text block integrity

This was done by inspecting the sampled item for any of a standard list of signs of physical deterioration (e.g., broken bindings) or environmental damage (e.g., mold, water damage) and assigning it to a general category of physical condition based on the presence or absence of these signs. (A description of the signs and categories appears in Appendix 3.)

(2) Extent of brittleness of paper

This was determined by performing the "fold test" on a corner of a middle page of the sampled item and recording the number of double folds made before the corner broke off. The fold test is the standard method of determining brittleness. (A complete description of the technique is included in Appendix 3.)

No chemical analysis was conducted on the samples. While desirable, collection of data reflecting paper acidity (as measured by pH) and lignin content are of secondary importance because it can be assumed that the vast majority of the collection contains paper with high-acid content. Staff performing the physical inspection and fold test on sampled materials received special training to ensure a uniform approach to the sampling.

Sample audiovisual media were checked for general physical condition, visual quality, and/or audio quality using standard criteria for deterioration of such media and assigning condition categories. Condition criteria include number of splices for films, quality of the color of images presented (i.e., good, off-color, faded), etc. Physical condition was determined by visual inspection of the media. Video and/or audio quality were determined by viewing or playing portions of the sampled programs on appropriate audiovisual equipment. In addition, videocassettes were evaluated using a microcomputer-based video tape evaluator/cleaning machine which can detect video and audio tape dropouts.

Results of the Survey

Table 1 summarizes the physical condition of the binding of all print materials. No environmental damage was found in any of the sampled items in these categories.

Table 1

Physical Condition of Binding and Text Block (%)

	Estimated Total Volumes	% of Sample With Damaged Binding	Estimated Total Vols. With Damaged Binding	% of Sample With Torn Pages	Estimated Total Vols. With Torn Pages
1800-1870 Monographs	40,000	26.3	10,500	5.7	2,300
1871- Monographs	465,000	2.9	13,500	1.7	7,900
1800-1870 HMD Serials	20,000	18.0	3,600	6.0	1,200
1871-1969 Serials (B3)	371,000	11.3	41,900	6.9	25,600
1970- Serials (B1)	278,000	0	0	0.5	1,400
1871- Serials (B2)	91,000	3.6	3,300	0.1	100
Pamphlets	7,200	14.2	1,000	1.2	100
Theses in HMD	6,400	6.2	400	2.9	200
Total	1,278,600	5.8	74,200	3	38,800

Bindings of monographs and serial volumes published between 1801 and 1870 show the highest rate of damage. In absolute numbers, the 1871-1969 serials include the majority of the damaged volumes.

Not surprisingly, the bindings of the serial collection on the B-1 level, which includes only the latest 15 years of publication, were found to be in excellent condition. The low incidence of damage (.5%) in this group of materials appears to indicate that the heavy use of photocopiers on the B-1 collection during the last five years has not had a significant negative effect on bindings.

Table 2 shows the physical condition of the unbound manuscript collection.

Table 2

Physical Condition of Modern Unbound Manuscripts

Condition	% in This Condition	Estimated Total Number of Boxes in This Condition
Good	45	1,220
Fair (Container damage and/or manuscripts have frayed edges or tears or presence of rusting metal clips, staples, etc.)	32	860
Poor (Frayed edges and rusting metal clips, etc., and/or manuscripts badly yellowed or damaged from insects, water, or mold, etc.)	23	620
TOTAL	100	2,700

A large number of the unbound modern manuscripts are in poor condition (wrinkled, torn, etc.) due to the way they were stored prior to their acquisition by NLM. Over 20 percent show some evidence of damage caused by mold. Again this appears to have occurred before NLM acquired the manuscripts because no mold damage was found in any other elements of the collection.

Table 3 summarizes the brittleness of all surveyed paper-based collections. In this table, "brittle" paper is defined as paper which broke off after two or fewer double folds in the fold test. This definition has been used by other research libraries which have conducted similar studies (2).

Table 3

Summary of Brittleness of NLM Paper-Based Collections

	% of Sample Brittle (2 folds or less)	Estimated Total Vols.	Estimated Total Vols. Brittle	Estimated Brittle Vols. Already Microfilmed
1800-1870 Monographs	12.1	40,000	4,800	500
1871-to date Monographs	11.7	465,000	54,400	1,100
1801-1870 Serials	20	20,000	4,000	900
1871-1969 Serials (B-3)	11.2	371,000	41,600	9,100
1970-to date Serials (B-1)	0	278,000	0	
1871 to date Serials (B-2)	5.5	91,000	5,000	
Pamphlets	15.5	7,200*	1,100	
Theses	33.5	6,400*	2,100	
Manuscripts	4.2	2,700**	100	
Total	8.8	1,281,300	113,100	11,600

* volumes or boxes

** boxes

Embrittlement, though serious, is not as widespread as was feared. From 1801 to date there are 1.28 million volumes of monographs, serials, pamphlets and theses in the NLM collection. Accounting for the proportional differences in the sizes of the various collections, the sampling indicates that there are approximately 113,000 brittle volumes, or 8.8%. The amount of brittle paper in other major collections far exceeds that found in the NLM collection. In a recent evaluation of the Yale print collections (2), 29% of the volumes sampled were found to be brittle, using the same criterion (2 or fewer double folds) applied in NLM's survey. LC estimates that 25% of its law and general collections is brittle, based on one or fewer folds in a fold test done by machine (3). It is not known how many manual folds are equivalent to one machine fold.

Table 4 summarizes the condition of the audiovisual collections that were surveyed. The term "off-color" refers to unrealistic fleshtones and colors of known objects; "faded" denotes that all objects are the same color.

Table 4

Medium	Physical Condition	Visual Quality	Audio Quality
Videocassettes (1960 - date)	100% good to excellent	some visual and audio dropouts but none affected quality of picture or sound.	
Audiocassettes (1970 - date)	99.7% excellent	--	98% good
16mm Films (1947 - date)	65% good	87% good	100% good
	30% fair	10% off-color	
		2% faded	
Film Strips (1968 - date)	98% good	87% good	--
		12% faded	
Slides (1950 - date)	97% good	95% good	--
		3% off-color	
		2% faded	

The audiovisual collections are generally in good condition. The principal exception is the 16mm film collection; over 35% of the films sampled had 4 or more splices. In addition, 12% of both the 16mm films and the film strips have suffered some loss of color.

Summary

The condition of the NLM collection is better than had been anticipated. With 8.8% or an estimated 113,000 volumes of its paper-based collections embrittled, NLM faces a smaller preservation problem than other research libraries, which have significantly larger collections of old material and percentages of brittle paper that exceed 25%. In general, NLM's audiovisual programs are also in good condition. By taking action immediately, NLM can ensure preservation of the content of the endangered volumes and also extend the life of the remainder of the collection. Delays may lead to the loss of already brittle materials and the increase in the number of brittle items requiring very expensive preservation techniques.

IV. PHYSICAL FACILITIES AND ENVIRONMENT

The physical facility and environmental conditions in which library materials are stored have a profound effect on the preservation of those materials. There are five environmental factors which affect the longevity of paper:

1. Temperature and Relative Humidity
2. Atmospheric Pollutants
3. Light
4. Mold
5. Insects and Rodents

Studies indicate that the lower the storage temperatures for printed materials, the longer they last. For every 9°F decrease, the useful life of the paper is approximately doubled. In areas where books and journals must coexist with humans, a temperature of 65°F is often recommended. A proper humidity level is also important. Excessive humidity promotes acid hydrolysis and biological attack by mold and bacteria, while lack of sufficient humidity promotes desiccation and possible loss of strength. Relative humidity levels of 45 (±5) percent are recommended for paper-based materials. Films and videocassettes benefit from cooler and drier storage conditions. A temperature of 50°F or less and relative humidity between 25-30 percent is recommended for such materials. Both temperature and humidity levels should be kept as constant as possible, to avoid the weakening of library materials which can result from cyclical variations in the climate in which materials are stored. Any changes should be infrequent, gradual, and less than 10°F in storage temperature and 10 percent in relative humidity.

Atmospheric pollutants such as sulfur dioxide, oxides of nitrogen, and ozone have been identified as harmful to paper. Compounds containing oxides of sulfur can combine with moisture to form sulfuric acid. Nitrogen dioxide and ozone are oxidants and thus accelerate oxidative degradation. Dirt and dust act as abrasives, and can actually imbed into the surface of paper. Additionally, such particulates can carry adsorbed sulfur dioxide and nitrogen oxides.

Light, both in the ultraviolet and visible frequencies, increases the rate of chemical reactions within paper. Some of the effects of light exposure are apparent, such as bleaching of colors and certain inks, and the darkening of paper to yellowish or brownish color due to a reaction of any lignins present with other chemical compounds. Unseen effects include oxidation, and the eventual breakdown of the cellulose chains in the paper's fibers.

While temperature, relative humidity, atmospheric pollutants, and light are considered to be the four primary environmental conditions affecting preservation, damage from mold or mildew and insects and rodents must also be avoided. Mold or mildew growth causes staining, loss of paper strength, and eventually the deterioration of the material itself as it is consumed by these biologic agents. Mold spores are found in the air and on books, and grow rapidly in stagnant air with a temperature of 80°F or above and a relative humidity in excess of 65 percent. Because paper is composed of a variety of organic substances, insects and rodents will feed upon it if other food sources are not available.

NLM's Physical Facility

From 1836 to 1962, the NLM collection was housed in a series of facilities, none of which provided a particularly good environment for the Library's materials. The major exception to this rule was the storage provided to the Library's pre-19th century books from 1942 to 1962 at the Allen Memorial Library Building of the Cleveland Medical Library Association. (For a description of the early facilities of the Library, see pp. 8-9 in Appendix 1).

The completion of the present Library building on the NIH grounds in 1962 provided the Library with greatly improved physical facilities. The five-story Bethesda building, measuring 276 feet by 192 feet and containing 231,560 square feet, is steel with exterior walls of limestone, granite and marble trim. Three floors of the structure are below ground, a precaution against the possible atom bomb attack envisioned by civil defense planners of the 1950's. This defensive planning led to the insertion of narrow, recessed windows on the main (first) floor and mezzanine. The top floor, the mezzanine, contains administrative offices; the first floor holds the main reading room, catalog area, history of medicine reading room and offices, and staff offices of members of the Technical and Reference Services Divisions. The bottom three levels, under ground, contain stack areas as well as work areas for staff of the Reference Services Division, Technical Services Division, History of Medicine Division, Bibliographic Services Division, MeSH Section, and RML Office.

At the current rate of acquisition of new materials, it is estimated that adequate space for the collection will exist for approximately twenty years. This time could be extended substantially by the installation of compact shelving on the B2 Level. To date the Library has received conflicting opinions as to whether the B2 floor is sufficiently strong to support compact shelving. Acquisition of an increasing number of materials in non-print formats and disposal of some printed materials after preservation copies are made will obviously affect NLM's space requirements for the collection.

The entire Library building is served by a single heating/ventilating/air conditioning (HVAC) system. Steam and chilled water are produced at a central NIH facility, and piped into the building. Eight air-mixing units serve different areas of the building. Air is drawn into the building from ground level vents located on the west side. Although it is an advantage that the building contains no furnace to generate internal pollutants, the location of the intake vents is often downwind from the central NIH power plant, found to the northwest. The existing HVAC system does not contain chemical filters. Mechanical filtration for dust and other particulate matter is accomplished in two stages through a bank of screen-type fiberglass filters, and then through fiberglass bag filters rated at 90% efficiency. Humidity can be both instilled into and removed from the air by the HVAC system, which is monitored and maintained by the building engineer, assigned by the NIH Division of Engineering Services.

Most of the lights in the building are fluorescent tubes. For the past several years, the majority of lights in the areas where materials are shelved have been covered with sleeves that block the emission of ultra-violet light.

The building is protected against fire by a water sprinkler system. The rare book collections (incunabula room and B1 stacks in HMD) are protected by a carbon dioxide fire extinguisher system. The Library has in the past considered replacing carbon dioxide with halon, which might present a lesser threat to the safety of employees, but no action has been taken in this direction. In accordance with the federal policy of "self-insured" protection, neither NLM nor its collections carry special insurance against damage or loss.

Facilities for exhibiting portions of the collections, which is done on a regular basis and frequently involves rare books, are not ideal. The cases used have locks, but would be easy to open. The plastic tops do not filter out ultraviolet radiation from natural or artificial light.

The Library's security system includes electronic surveillance and a search of bags, briefcases, etc. by a guard as patrons and staff leave building 38. Large portions of the collection, including rare books and manuscripts, are not provided with security labels and would therefore be undetected by the electronic security system. Access to the historical collections is more restricted, however, than access to the general collections. There is no evidence that loss by theft has been great over the years, but the theft of an infrequently used item can go undetected for a long time.

Environmental Conditions at NLM

Since there was little available data on environmental conditions in the NLM building, a survey of these conditions was also an important part of the preservation planning process. The Task Force on Environmental conditions, assisted by staff from NIH and the National Bureau of Standards, collected a variety of data throughout the Library.

Survey Methodology

The areas examined were:

1. First Floor
   a. Main Reading Room
   b. History of Medicine Reading Room
   c. Prints and Photographs Collection
   d. Incunabula Room

2. B1 Level
   a. General Collection Stacks
   b. History of Medicine Collection stacks

3. B2 Level
   a. General Collection Stacks
   b. History of Medicine Collection Stacks
   c. Cold Storage Vault

For each of these areas, the following information was gathered:

1. Division and Section of the Library responsible for maintenance
2. Usage
3. Area in square feet
4. Ceiling description
5. Lighting method
6. Floor covering
7. Wall covering
8. Shelving type for materials housed
9. Fire protection
10. Miscellaneous pertinent facts

The Task Force identified six major environment-related parameters to examine: (1) temperature (2) humidity (3) light (4) atmospheric pollutants (5) cleanliness (6) shelving structures.

Temperature and relative humidity data were gathered using nine Honeywell recording hygrometers (Model 612X9). Each instrument was calibrated using a sling psychrometer. These nine units were located at representative sites--with electrical outlets available nearby as well--in the following areas:

1. Reading Room, first floor
2. General Collection stack area, B1 level
3. General Collection stack area, B2 level
4. General Collection stack area, B3 level
5. History of Medicine stack area, B1 level
6. History of Medicine stack area, B2 level
7. Incunabula Room first floor
8. Prints and Photographs Collection, first floor
9. Cold Storage Vault, B3 level

Recording began for most units on December 23, 1984, and has continued since that time. Data for each Sunday, Wednesday, and Friday, at 8:00 a.m., 1:00 p.m., and 5:00 p.m. were extracted from the recording charts of the hygrometers. It was determined that no acceptable source of previously gathered temperature and humidity data was available to compare with data from the present study. Ambient temperature and relative humidity readings, daily highs and lows at National Airport, were obtained from the U.S. Weather Bureau, and from the daily weather review in the Washington Post.

In general the temperature levels were found to be quite stable throughout the areas examined, within a range of 60°F to 73°F, which compares favorably to the frequently cited standard of 65°F ± 5°. One exception was the History of Medicine Prints and Photographs Collection room, which consistently was warmer, at approximately 74°.

In contrast to temperature conditions, relative humidity levels varied widely, from a low of 20% to a maximum of 45%. This range is well below the optimal level of 45-55%. Many of the lower readings occurred in the History of Medicine areas. In investigating this situation, the Task Force discovered that air mixing unit number seven, which serves that area, has no humidification capacity. All other mixing units have appropriate humidification equipment. Although not observed by Task Force members, it was noted by NLM staff that condensation tends to form above the cold storage vaults, especially during summer months.

Lighting conditions were assessed on the B1, B2, and B3 levels in the stack areas, and in the main reading room, at the same locations where the recording hygrometers were positioned. Lights are primarily fluorescent tube units, with conventional on-off switches mounted locally on the wall. Most lights in the stack areas are covered by ultra-violet blocking tubes. Light intensity measurements were taken by NIH Division of Safety staff using a Weston Foot-Candle Meter. Ultra-violet radiation levels were measured by members of the environmental conditions Task Force using a Crawford UV Monitor Type 760/L. The readings were made on a one-time basis--the artificial light sources for the underground levels remain constant, while the reading room varies somewhat based on external sun light levels.

Results of the lighting measurements indicated that the overall intensity and proportion of ultra-violet radiation were well within recommended levels. In the stack areas, the intensity levels ranged from 13-20 foot-candles (130-200 lux). In the reading room the measurement was 65 foot-candles. This latter level is above the recommended 30-50 foot-candle range, but was recorded on a bright sunny day. The ultra-violet radiation proportion was 25 uW/lumen throughout, compared to a maximum recommended level of 75 uW/lumen. UV readings taken directly beneath a bank of unsheathed fluorescent bulbs showed twice the level compared to sheathed bulbs, 50 uW/lumen. UV readings taken near windows in the reading room and lobby areas shows UV proportions of 60-75 uW/lumen but dropped off very rapidly as the instrument was moved toward the interior of the room. Measurements in the Learning Resources Center and some of the processing areas were very similar to those taken in other areas where the collection is stored.

Atmospheric pollutants including sulfur dioxide (SO_2), nitrogen dioxide (NO_2), hydrogen sulfide (H_2S) and ozone (O_3), were sampled by NIH Division of Safety staff using a Mine Safety Appliance (MSA) Universal Tester Pump with the appropriate MSA detector tubes. These tubes are certified for the following accuracy ranges by the National Institute for Occupational Safety and Health (NIOSH).

Sulfur dioxide: 2.5-25 parts per million (by volume)
Nitrogen dioxide: 2.5-25 PPM
Hydrogen sulfide: 5-50 PPM
Ozone: 0.5-4 PPM (not certified by NIOSH)

Samples were taken on the B1, B2, and B3 levels, and in the main reading room at the same locations where light intensity and temperature/humidity data were gathered. Given the sensitivity of the MSA tubes as described above, presence of the four specified atmospheric pollutants was not detected.

To determine the actual levels of concentration of atmospheric pollutants required more sensitive equipment. Experts from the National Bureau of Standards (NBS) were engaged to measure the baseline presence of sulfur dioxide, oxides of nitrogen, and ozone. At their recommendation, testing for hydrogen sulfide and hydrocarbons was not done, as it was not considered necessary. Highly sensitive instruments were brought into the building and calibrated. Readings were recorded between April 8 and April 15, 1985 in the B2 stacks, and in the main reading room on the B1 level. Ozone was also measured in the photocopy room on the B1 level.

Table 5 summarizes the environment-related quantitative data gathered and compares them to the recommended levels for the various parameters and atmospheric pollutants. (Appendix 3 is a copy of the full NBS air quality report.)

Table 5

Parameter	NLM Condition	Recommended Range	Source of Recommendation
Temperature	60°F - 73°F	65°F ± 5°F	a/
Relative Humidity	20% - 45%	45 - 55%	a/
Light Intensity	13-20 foot-candles (stacks) 65 foot candles (reading room)	maximum of 30-50 foot candles	a/
Ultra-violet proportion	25 uW/lumen	less than 75 uW/lumen	a/
Atmospheric Pollutants			
Sulfur dioxide	Avg. 6 ppb b/ Max. 49 ppb Min. 0 ppb	from 0 to 4 ppb	c/
Nitrogen oxides	Avg. 44 ppb Max. 208 ppb Min. 22 ppb	from 0 to 5 ppb	d/
Ozone e/	Avg. 4 ppb Max. 17 ppb Min. 1 ppb	from 0 to 13 ppb	f/

a/ Darling, Preservation Planning Program: An Assisted Self-Study Manual for Libraries (ARL, 1982) (4)

b/ Parts per billion (by mole).

c/ The British Museum (5,6,7) and the Royal Ontario Museum (8) recommend complete removal, while Banks (9) and Thomson (7) recommend 4 ppb. NBS Workshop on Environmental Conditions for Archival Storage recommended 2 ppb. (10)

d/ The British Museum (5,6,7) and the Royal Ontario Museum (8) recommend complete removal, while Thomson (7) recommends 5 ppb for nitrogen dioxide. The NBS Workshop (10) recommended 2.5 ppb for nitrogen dioxide.

e/ Ozone measurements summarized in this chart were taken in areas where the collection is stored. Ozone measurements were also taken in the photocopier room serving the reading room. The existing copiers clearly were a source of ozone; levels ranged from a minimum of 2 ppb during off-hours, to a maximum of 62 ppb during peak-usage hours. Average ozone level was 14 ppb.

f/ The British Museum (5,6,7) and the Royal Ontario Museum (8) recommend complete removal, while Thomson (7) recommends 1 ppb. The NBS Workshop (10) recommends 13 ppb.

Members of the Task Force on Environmental Conditions also conducted a walk-through of the spaces to assess cleanliness and shelving conditions. They found that housekeeping services were inadequate in the stack areas, as evidenced by levels of dust and dirt found on the floors and on shelving units. No testing for biologic agents such as mold or bacteria was conducted. Shelving units and bookends currently in use do not damage the collection. However, the number of book trucks and step stools available to transport and access materials is insufficient.

Smoking, drinking, eating and the cultivating of plants are common in many work areas throughout the Library and while these practices can be a potential hazard to library materials, no serious or widespread damage was discovered. Policies restricting these activities do exist for the stack areas, the public Reading Rooms, and HMD staff areas. Insects and rodents are not a problem in the Library.

Summary

Although there are some problems, in general the environmental conditions in the Library are good and probably can be improved without great expense. The construction of the Library, with relatively few windows and three floors below ground, makes it easier to maintain appropriate temperatures for the collection and to minimize the amount of ultra-violet radiation. Concern for the preservation of the collection is evident in the design of the building and in its heating and air-conditioning system.

The environmental survey has already prompted several specific actions to improve conditions for the collection. These include: a work order request to add humidification and dehumidification (if necessary) capacity to air-mixing unit number seven which, unlike all the other units, has never contained a humidifier; arrangements made by OAMS for housekeepers to dust the floors and stacks weekly and to wet mop monthly; a request to OAMS to install ultra-violet blocking tubes on all unshielded fluorescent bulbs in areas where the collection is stored or processed; a work request to the NIH Division of Engineering Services to install insulation above the cold storage vaults; and purchase of additional step stools and replacement book trucks.

V. COLLECTION USE AND MAINTENANCE

The amount and nature of physical processing, handling and use of Library materials by staff, and patrons have an effect (either positive or negative) on the life of those materials. Some negative effects are chemical: for example, inks or adhesives used in marking may react with the materials. Most effects are physical, affecting the external structure of an item: bindings may be broken; paper and film torn; magnetic tape stretched, scratched, torn or erased. The susceptibility of materials to this kind of damage depends upon both internal and environmental factors. Paper embrittled through chemical reaction will disintegrate at a touch; a tight adhesive binding will split when opened under hot, dry conditions; a film subjected to extreme fluctuations in temperature or humidity will shrink.

The mission of any library is almost inevitably hostile to the preservation of its contents, for materials are acquired, organized and stored primarily to be used, and use necessarily takes a toll on condition. There will always be a tension and compromise between the need to preserve materials and to make them readily available to the Library's users.

Processing

Materials arrive at the National Library of Medicine from all over the world. Books and journals from some foreign countries arrive in poor physical condition due to the environmental or physical conditions under which they were transported, or the inferior quality materials of which they are made. Books received from the Library of Congress, 2%-10% of which are added to the NLM collection, are sent in canvas bags and bins and often show signs of damage. All materials receive a good deal of handling in processing. Items are checked in; subjected to the insertion of a wide variety of forms between their leaves; cataloged, and in some cases indexed, either inhouse or by contractors outside the Library; stamped; marked; labelled with security labels and machine readable identifiers; sent to be bound if necessary; and shelved. Some overcrowded processing areas and work stations increase the risk of damage to incoming materials.

Storage

Most of NLM's collections are housed in metal stacks. Journals from the period 1871-1969 are stored in compact shelving, and it is anticipated that over the next two years many more items will be transferred to existing or newly-installed compact shelving. Certain collections are stored under special conditions. Archival microfilm and the historical film collection are preserved in special cold storage vaults. Acid-free document boxes and folders are used to house the collections of papers in the Modern Manuscripts collection. Fine art prints are stored flat in special cases. Overall, NLM's storage conditions are good.

Binding

Binding is a measure intended to protect library materials. Both binding preparation and the actual binding of NLM's post 1870 books and journals are done on contract. The preparation contractor collects loose journal issues and controls the shipment of those issues to and from the commercial binder. NLM currently is required to use a central binding contract for the Department of Health and Human Services that is administered by the Government Printing Office. The specifications for the binding are set and the contractor selected by GPO. Journals and soft-bound books are bound with a class A binding (standard library binding), and acid-free end papers are used.

Use

While most materials in the Library's collections are stored in a closed stack environment, the majority of them are accessible to patrons onsite in the public Reading Rooms and the Learning Resource Center or through NLM's interlibrary loan service. Onsite circulation includes provision of the original item to the patron, whether it be a journal issue, a book or an audiovisual, unless the original item is in very fragile condition. In FY 1984, over 191,000 items were provided to Reading Room and History of Medicine patrons. Items housed in the Reading Rooms are directly accessible by readers, with perhaps as many as 86,000 uses made each year, based on estimated reshelving counts. In addition to the normal wear and tear of handling by both staff and by patrons, heavy and unsupervised use is made of the self-service photocopy machines (1.1 million exposures were made by patrons in FY 1984), and audiovisual materials are used on LRC playback equipment, most of which is more than 10 years old. Both types of use are known to shorten the life expectancy of the materials.

The majority of interlibrary loan requests are for current journal articles and are filled by sending out staff produced photocopies. Nearly 103,000 articles were photocopied in FY 1984. Books and audiovisuals from the general collection are regularly sent out on interlibrary loan to requestors. These original loans numbered 10,700 in FY 1984. The History of Medicine Division also sent out some original items on loan, but most of the 2000 requests in FY 1984 were filled as photocopies or on microfilm. In the latter case, a microfilm master is retained for future NLM use.

Added to the actual patron use of library materials is the staff handling which goes into providing items to a patron, and the necessary reshelving of items following use. Conservatively, the total handling count for fulfilling NLM's service mission could be over 1 million uses annually, concentrated on a relatively small portion of the entire NLM collection.

Education

Staff and user handling techniques are influenced by the presence or lack of instruction and policies. Instruction and monitoring of all processing and service within Library Operations focuses on intellectual and not physical handling, with few written guidelines for the latter. No instruction for NLM patrons (either onsite or remote) is currently conducted.

Summary

The results of the survey of the physical condition of items in the NLM collection indicate that current processing and use practices are not having a serious negative effect on the Library's materials. This does not mean, however, that there is no room for improvement in the way NLM's collection is handled by staff and users. The process of observing, documenting and discussing the use and processing practices that can affect the Library's collections has already caused staff members to be more preservation conscious and alert to potentially damaging handling policies and techniques. Some physical damage is unavoidable in a service organization where use is expected and encouraged, but steps can be taken to reduce even further damage during processing and after the materials are in the users' hands.

As a result of this study several steps have been initiated or are planned to reduce unnecessary wear and tear on library materials. These include: reviewing the number and type of preliminary forms that are inserted in library materials as they are processed; assuring that all labels and markers used are as benign as possible; ceasing the use of metal paper clips to mark pages; redesigning the Reader Service sorting area to be more efficient and reduce jumbles of materials; purchasing dust covers for all audiovisual and microfilm equipment and developing a plan for routine preventive maintenance as well as phased replacement of such equipment; and ensuring that the serial issue in the best physical condition is bound, when more than one copy is available on the shelf.

VI. PRESENT LEVEL OF PRESERVATION ACTIVITY AT NLM

NLM's current preservation activity consists primarily of binding serial issues and paperbound monographs, collection maintenance, and special preservation of rare books and archival films. From 1966 to 1982, with a combination of in-house staff and contract support, the Library microfilmed runs of about 2,000 early Index Medicus serial titles and 3,000 - 4,000 monographs, principally from the period 1871 to 1906. This program was suspended because of the high cost of microfilming, the promise of new preservation technologies and the lack of a plan for assigning preservation priority to the remaining items in the collection. At present, only about 172,000 pages are microfilmed in-house each year. The majority of these are filmed to fill interlibrary loan requests for materials in the historical collections which cannot be loaned in the original.

The Library first developed a Disaster Recovery Plan and assembled special supplies and procedures for handling disasters affecting the collection in 1979. The plan has been revised periodically, most recently in conjunction with the development of this Preservation Plan.

Responsibility for current preservation activities is divided among the Reference Services Division (RSD) and the History of Medicine Division (HMD). The following chart summarizes staff and other resources devoted to ongoing preservation activities in FY 1985. The figures exclude: (1) administrative overhead in the offices of the Chiefs, RSD and HMD, and the Associate Director for Library Operations; (2) the NLM staff time devoted to the preparation of the Preservation Plan; (3) a proportional share of the NIH Management Fund; and (4) Office of Computer and Communications Systems expenditures that can reasonably be assigned to automated support of current collection maintenance, binding, and microfilming activities.

Table 6

NLM Resources Allocated for Preservation - FY 1985

Staff Support

	NLM FTE	Budget
Reference Services Division		
Circulation and Control Section	7.25	138,100
Audiovisual Resources Section	1.5	28,400
History of Medicine Division	2.4	51,700
Total	11.1	218,200

Other Expenditures

Binding Preparation Contract	253,500
GPO Binding Contract	184,000
Compact Shelving purchase	55,300
Preservation of archival films	135,000
Rare book binding	40,200
Manuscript rebinding	60,000
Consultants - preservation plan, air quality sampling, evaluation of prints and photographs collection	11,500
Other miscellaneous - equipment, equipment maintenance, supplies, etc.	32,600
Total	772,100
Grand Total	990,300

VII. CURRENT STATE OF PRESERVATION TECHNOLOGY

In the broadest sense, any activity that extends the life of library materials is a preservation technique. This is why the enhancement of the environment in which materials are stored and improvements in the way materials are handled are important to any preservation program. Using a narrower interpretation, however, a preservation technique is something that improves the intrinsic durability of an item or creates a copy of it in a more durable medium. Relatively few such techniques exist, particularly for mass preservation of the post-1850 printed materials which are most at risk. Fortunately, recent expansion of interest in preservation among research libraries has sparked research in mass preservation techniques. Although currently available options are still very limited in number, there is promise of better things to come.

A description of the major techniques that are currently available or are the subject of research activity follows, with an estimate of their costs, if reasonable estimates are possible.

a) Mass Deacidification

Manual deacidification methods, involving immersing the pages of a disbound book or the brushing/or spraying of each page with a deacidification agent, have been in use for some time by paper conservators. These traditional single-sheet methods are too slow and expensive for NLM to apply on a large scale, although they continue to be appropriate for rare books, manuscripts and art prints. Newer mass deacidification procedures promise a more affordable means of extending the life span of paper-based materials by as much as four to five times the life of the paper before it was treated. This could be two to three hundred years for some materials. The newer the materials are at the time they are deacidified, the more they can benefit from the process.

There are two mass deacidification procedures which have received extensive testing, the Wei T'o liquefied gas mass deacidification process in use at the Public Archives of Canada and the diethyl zinc gas deacidification (DEZ) process of the Library of Congress. At the moment, the facility at the Public Archives of Canada is the only mass deacidification center in operation. Since 1981, six million pages from the Public Archives and from the National Library of Canada have been deacidified at this facility, using the Wei T'o method. The estimated cost of building a Wei T'o facility is at least $500,000 and would be considerably higher for the capacity needed by NLM. The U.S. Congress has appropriated $11.5 million for the construction of a DEZ facility at Frederick, Maryland for the Library of Congress. Scheduled for completion in 1987, this facility should have an annual capacity of 500,000 to 1,000,000 volumes.

The estimated cost of actual deacidification of a book by either the DEZ or Wei T'o method, which is now about $3.50 per volume, is expected to drop to $2.25 or less per volume in a fully operational, efficient plant. Preparation and transport of materials to and from a locally available facility will cost an additional $2.00 per volume, for a total of $4.25 per volume. NLM's cost per volume will be higher if the Library is required to pay for all or part of the cost of the construction of a mass deacidification facility.

The relatively low cost of mass deacidification, as compared to the cost of mass disk storage or microfilm, makes it an attractive preservation technology. Deacidification has the advantage of preserving materials in their original format, if that is important. It is also not subject to any copyright restrictions. Deacidification is of no use, however, for that portion of the collection which is already embrittled, as it can only halt and not reverse the process of acid deterioration of paper. It also offers no solution to storage space or remote access problems. In any case, mass deacidification will not be available to NLM before 1988 or 1989. That is probably the earliest date that NLM could arrange to begin using a portion of the LC DEZ facility, or to obtain deacidification services from other sources.

(b) Strengthening of Paper

There are several experimental processes designed to strengthen paper. One method deposits a strengthening agent in a vacuum at room temperature without catalysts. Another uses an acrylic copolymer and initiates polymerization with a radioactive source. This technology is not available to NLM for current use, even for individual rare items, and, in its present forms, would cost $50-$75 per volume. The level of research interest in this technique is increasing, however, and it may become viable and cost-effective for mass preservation in the future. The Department of the Treasury is interested in applying one of the strengthening processes to the one dollar bill, and LC's Preservation Office also intends to look at this technology.

(c) Mass Disk Storage

Mass disk storage involves electro-optically scanning original materials and storing the images on another medium and is therefore suitable for preservation of materials that are already brittle. The electronic storage of information in digital form on optical digital disks appears to have great promise for preservation. The advantages of the disk medium include high storage density, rapid random accessibility, and compactness. The major attributes of image signals in digital form are: the ability to regenerate, compress, or enhance the images stored and to convert bit-mapped imagery into machine-readable text. There is no generation loss in the transfer of the signal from one disk to another, as occurs in copying microfilm. The method offers exciting opportunities for linking bibliographic information (such as a MEDLINE or CATLINE citation) to the automatic retrieval and display of document images. The Lister Hill Center has demonstrated such a link-up of citations retrieved from NLM's mainframe computer and electronic document images stored on magnetic disk. Mass disk storage has the potential to play an important role in preservation in the next several years, especially for frequently used materials that would benefit most from increased ease of access and for materials originally published in machine readable form.

Although both LC and NLM have developed prototype systems to support research in the use of disk technology for information storage, access and preservation, the preservation potential of the disk medium is not yet clearly understood. Before an operational disk preservation system can be put in place, additional research is necessary to answer several basic questions about the technology, including the effective life expectancy of the disk (current estimates are 10 to 30 years), the most effective compression techniques, and the methods for monitoring image quality in a production environment. The answers to these and other questions will have a significant effect on the cost of preservation on disk. Since most commercial interest in disk technology relates to its erasability and reusability, NLM and LC may not be able to rely on the private sector to fund research into the preservation properties of the medium. It is unlikely that NLM will be able to use optical disks for large scale preservation in the next two to three years, given the present uncertainty about the preservation characteristics of the medium and the total system cost of a disk operation.

The general use of disks for preservation, at least for post-1906 materials, depends not only on technological advances, but also on the resolution of complex questions about intellectual property rights. Because it permits multiple and remote use of single copies of works, disk technology is perceived as a greater threat to the rights of copyright owners than preservation on microfilm.

(d) Microfilming

Microfilm, like mass disk storage, is a suitable preservation medium for printed materials that need not be preserved in their original format or have deteriorated to the point where preservation in the original format is not currently possible. When processed properly and stored under "archival" conditions, silver halide film is expected to last indefinitely. Proper storage requires special conditions (e.g., low temperature). Microfilm, like disk, offers the advantage of compactness. Unlike disk, it is not easy to access and use. Microfilmed images may be transferred to disk effectively, although the production costs of high volume transfer are not yet known.

The cost of microfilming an average volume is $40.00-$50.00, including $0.15 per exposure (for two printed pages) for the original master, $3.50-$4.50 for the service master and the diazo service copy, and $9.00 for preparation costs and recording preservation data. The price per volume is therefore at least several times the cost of deacidification. Although it is not yet possible to estimate the production cost of preservation of print materials on disk, that cost is unlikely to be significantly lower than the cost of microfilming. Preparing documents and capturing images, which are the major cost factors in microfilming, are also likely to be the major cost factors for disk preservation, given the same decision regarding the retention or destruction of the original being copied.

Although the ease of accessing materials on disk and the possibility of tying access to bibliographic information suggests that optical disk technology may eventually surpass microfilm as a preservation medium, microfilm will probably continue to play a significant role in preservation for some time to come. Microfilming is in fact the only method now available to NLM for large-scale preservation of paper-based materials. Even in the future microfilm may continue to be an acceptable preservation medium for infrequently used material.

(e) Film to Film Transfer

At present the preferred method for preserving films is film to film transfer with no reduction in gauge (i.e., 35 mm to 35 mm; 16 mm to 16 mm). Black and white archival triacetate film has an estimated longevity of 300 years when stored under archival conditions. Color film is more difficult to protect, but an "archival" color film on triacetate with an estimated longevity of 100 years is being used to copy films. Films should be copied to an internegative film master, with the internegative then used to make an answer print or service copy. The internegative master can then be used to produce another answer print when the service copy is worn, thus prolonging the life of the original. The cost per film for this procedure averages from $500 to $600. The original masters require storage in a climate controlled vault. To make NLM's historical films accessible to more users, it may also be advisable to make video viewing copies for films of particular interest for research or teaching.

(f) Preservation Methods for Special Collections

Special collections are defined as pre-1801 printed literature (and any later printed works which are considered to be rare or of exceptional historical significance), manuscripts, and prints and photographs. These collections contain the bulk of the items in the NLM collection that must be preserved in their original format and also the majority of items that require special individual handling during preservation. Preservation techniques for these materials include: oiling of leather bindings; hand rebinding and repair; individual deacidification; placement of materials in acid free folders and boxes, reconstruction of pages, encapsulation, etc. Any of the mass techniques described for post-1801 materials may also be appropriate for some materials in these collections, although greater care may be necessary to prepare the materials for preservation. Costs vary greatly depending on the condition of the original items and the specific technique chosen. The techniques are generally labor intensive and therefore expensive.

(g) Acquisition of Materials in Archival Formats

Although not strictly a preservation technique, the acquisition of new library materials made from substances with archival properties can be a cost-effective way of ensuring preservation of parts of a library's collection. Until recently, acquisition of materials in microform was the only choice available. With the development of a standard for "acid-free" paper and increased publication in machine-readable form, libraries may have increased opportunity to buy materials in archival formats--or at least in formats that are more easily and cheaply preserved.

Summary

When it becomes available, mass deacidification will probably be the cheapest alternative for preservation of paper-based material at an estimated cost of $4.25 per volume, ($2.25 for deacidification and $2.00 for preparation and transport.) The charge will be higher if all or part of the cost of constructing a deacidification facility is borne by the Library. Deacidification offers no space savings, but preserves the original artifact. With some effort, NLM should be able to obtain appropriate deacidification facilities by 1988 or 1989. Procedures for strengthening of paper are still in a very experimental stage, but could become practical in the future.

Mass disk storage has exceptional use characteristics, including random access, simultaneous use by multiple users, and the ability to link directly to automated bibliographic records. Because of these use characteristics, disk storage is more problematic than other techniques in regard to intellectual property rights. The preservation characteristics of disks are not fully understood and require further research. The results of such research are needed before accurate total cost estimates for preservation on disk can be developed.

Of the preservation techniques suitable for the mass of NLM's paper-based collections, only microfilming, at an average cost of $40-$50 per volume, is available to NLM today. Microfilm is very space-efficient if the original is not retained after filming, but it is also unwieldy to use.

There are generally accepted "best" methods for preserving segments of the audiovisual collections and the special collections (i.e., rare books, print and photographs, modern manuscripts). Because these methods involve skilled labor, they tend to be expensive--from fifty to several hundred dollars per volume or program.

In the future, acquisition of new materials in archival formats may reduce the required level of preservation activity and expenditure.

VIII. OTHER EXTERNAL FACTORS AFFECTING NLM'S PRESERVATION PROGRAM

NLM's preservation program must take into account a number of external factors affecting the U. S. information and biomedical communities, in addition to the current state of preservation technology. These include publishing trends, developments in the concept of intellectual property rights, changes in the ways health professionals acquire and use information, and the emergence of preservation as a critical concern in research libraries, which in turn has led to increased emphasis on cooperative library activities and the recent developments in preservation technology already described.

PUBLISHING TRENDS

Publishers are the primary source of NLM's raw materials--the books, periodicals, audiovisuals, prints and other library materials that make up the Library's collection. The worldwide publication industry determines the scope of the preservation problem that NLM will face.

For over a 100 years the trend has been toward lower cost, higher speed production of an ever increasing flood of publications, which, because of the acid paper, adhesives and binding techniques used in their manufacture, are subject to rapid deterioration. As the library community has become more aware of the inherent weakness of the materials it collects, it has attempted to persuade publishers to shift to methods that will ensure more durable products. Partially as a result, the National Information Standards Organization (NISO) has published a standard for permanent durable paper with an alkaline reserve. The availability of this standard could stimulate more acid-free paper production and provide a basis for influencing publishers to use it.

The definition of a "publication" has changed with the emergence of new media. An increasing amount of material is published in microform, especially computer-output-microfiche (COM); however, this medium too is subject to gradual destruction. Audiovisuals and electronically-based forms of information are proliferating daily and will present the Library not only with bibliographic, acquisition and service problems, but also with a different set of preservation problems.

INTELLECTUAL PROPERTY

Related to publishing trends are a spectrum of issues concerned with intellectual property rights. The question of who shall be reimbursed for what kinds of use of what kinds of "publications" is under continuing review as information becomes an increasingly valuable commodity. This in turn could affect the form and conditions under which publications may be reproduced for preservation purposes.

Although the matter has not been tested in the courts, informed legal opinion holds that copying deteriorating print materials on microfilm in order to preserve their content in a library or archives can be considered a "fair use" of copyrighted works if there is no financial gain associated with the copying. The argument is particularly strong for NLM as a national library with statutory responsibility to preserve the biomedical literature.

Since material preserved on disk is available for simultaneous use and can be redisseminated much more easily than material on microfilm, the use of disk technology for preservation adds dimensions to the discussion about intellectual property rights. On the other hand, electronic technology also offers a far more reliable and consistent way of collecting statistics on use. This could make the property rights issue easier to resolve, since actual use may be monitored automatically.

CHANGES IN THE WAY HEALTH PROFESSIONALS ACQUIRE AND USE INFORMATION

Health professionals traditionally have demanded rapid access to information. Health sciences librarians traditionally have responded by providing the best or developing the newest in information services. In the last ten years microcomputer technology and the proliferation of online databases have profoundly affected the way health professionals acquire and use information. Artificial intelligence systems, electronic publishing, and developing "electronic colleges" have the potential for making even more significant changes. If current trends in hospital economics continue, there will be fewer libraries available close at hand to fill immediate needs. It is likely that there will be increasing numbers of technologically sophisticated physicians tapping into remote information resources both for current and older materials. The challenge to NLM then is not just to preserve the biomedical literature, but to preserve and store it in ways which will facilitate access for the user community and be appropriate to their changing needs.

EMERGENCE OF PRESERVATION AS A CRITICAL CONCERN IN RESEARCH LIBRARIES

Over the last 25 years the Council of Library Resources (CLR) has acted as a catalyst to focus attention on preservation as a critical concern. In large measure as a result of CLR's efforts, significant progress has occurred in several areas. There is a developing consensus on the size of the preservation problem which libraries collectively face, a recognition of the cost of confronting it and of the cost of failing to confront it. There is also a significant research effort which addresses methods to prevent or retard deterioration of library materials and methods for mass storage of copies of already deteriorated materials.

Preservation has emerged as a specialty within the library profession. Interest and expertise has spread beyond the circle of archivists and rare book librarians. The pool of trained and partially trained preservationists is expanding as is the demand for this type of expertise.

Funding of preservation projects by CLR, the National Endowment for the Humanities, and charitable foundations is increasing. Library organizations such as the Association for Research Libraries and the Research Libraries Group are taking advantage of available funding to stimulate preservation planning among research libraries and to develop cooperative preservation programs, including regional preservation centers.

The Library of Congress has established a National Preservation Program Office to provide information, educational support, and coordination among the many institutions engaged in preservation activities around the country.

Clearly the climate is favorable for NLM to expand its own preservation program and to work with other institutions to develop useful cooperative preservation projects.

IX. RECOMMENDED STRATEGIES FOR PRESERVATION AT NLM

An examination of the current condition of the NLM collection, the environment in which it is stored, the way its materials are processed and used, and the present level of preservation activity has revealed a preservation problem that can be solved if NLM takes immediate action to establish a comprehensive preservation program. In many respects, NLM is in a much better position than other U.S. research libraries which have such huge numbers of brittle materials that there is almost no possibility of saving them at all. Due to the relatively good condition of the NLM collection and its manageable size, NLM has the opportunity to fulfill its mandate to preserve the biomedical literature.

After careful evaluation of available options, the Preservation Planning Team recommends that NLM take the following actions to create a preservation program capable of ensuring the long-term availability of the scholarly record for biomedicine.

A. MODIFY THE NLM BOARD OF REGENTS' POLICY ON PRESERVATION

The NLM Board of Regents' policy on preservation of the collection should be modified to link NLM's preservation program more explicitly to its collection development guidelines, to clarify the Library's responsibility for the preservation of the content as opposed to the format of the biomedical literature, and to define NLM's role in assisting the preservation of significant biomedical literature held by other U.S. libraries.

The Preservation Planning Team recommends that the new policy encompass the following principles:

> NLM should assume primary responsibility for the preservation of the core biomedical literature that the Library collects at the comprehensive level and should share with other research libraries responsibility to preserve literature in subjects related to medicine and health that it collects at the research level. NLM must ensure that the biomedical literature is preserved, but need not do all the preservation work itself.
>
> NLM should seek to preserve the biomedical literature irrespective of the format (e.g., print, audiovisual, machine readable) in which it is published, but the Library's primary preservation responsibility is for the content of that literature rather than its format.
>
> In making decisions regarding the order in which materials are to be preserved, NLM should give consideration to: the uniqueness of the material, its level of use, its state of deterioration, the existence of preservation copies elsewhere, the relationship of the material to existing cooperative preservation activities, and the availability of suitable preservation techniques. NLM should

monitor developments in preservation techniques and should participate in research, development, testing, and evaluation of preservation technology. In selecting preservation techniques, NLM should consider the likely future demand for the material, ease of use of the preserved original or preservation copy, the cost and reliability of the preservation method, and the cost of the long-term storage of the archival copies.

The Preservation Planning Team has prepared a draft policy statement for consideration by the Director, NLM and the Board of Regents. The full text of this draft statement is included in Appendix 5.

B. ESTABLISH A NEW ORGANIZATIONAL UNIT TO DIRECT NLM'S PRESERVATION PROGRAM.

NLM's existing preservation organization, while appropriate for the level of preservation activity currently underway, is inadequate to handle the expansion of preservation functions that the Library must undertake to ensure the preservation of the scholarly biomedical literature. What is needed is an organizational unit specifically devoted to preservation that can provide a focus for all NLM preservation activities and assume direct responsibility for many of them. Given present constraints, the new unit must be developed within existing ceilings for budgeted positions and FTEs. It should also continue NLM's current practice of contracting out most of the actual physical preservation or copying of materials to archival formats.

After examining several different options for NLM preservation organizations, the Preservation Planning Team recommends that a Preservation Section be established within the existing Reference Services Division. The core of the new Section should be formed by bringing together staff throughout Library Operations who now have preservation responsibilities. The Preservation Section will provide an operational focus for NLM's preservation program by initiating and managing the expansion of the level of preservation activity at NLM; monitoring developments in preservation technology and selecting appropriate techniques for the NLM collection; training staff and users in safe materials handling; developing cooperative preservation programs; and assisting in the identification of appropriate preservation research projects. While the Preservation Section will have major responsibility for NLM's preservation operation, the History of Medicine Division will continue to perform important preservation activities related to the special historical collections. The Lister Hill Center will conduct actual research related to preservation. (See Appendix 6 for a more specific rationale and list of recommended functions for the new Section.)

C. EXPAND THE LEVEL OF PRESERVATION ACTIVITY AT NLM

Because NLM has the largest collection of biomedical literature in the world, preservation of the materials held by the Library represents a significant step toward preservation of the entire scholarly record in the field of medicine and health. Since 1982, NLM's preservation activities have been limited to binding current materials, treatment of segments of the special collections, and preservation of archival films. With the completion of this comprehensive study of internal and external factors affecting preservation of the NLM collection, the Library should expand its preservation program to achieve by the year 2005 the goal of a preservation copy for every item in the NLM collection that falls within the subject areas that NLM collects at the comprehensive or research levels. NLM should take the following specific steps toward this goal:

C.1. Obtain by 1989 mass deacidification service for 100,000 NLM volumes annually.

Data on the condition of the NLM collection indicate that of 1.28 million volumes, at least 91.2% or 1.17 million volumes (boxes of theses or pamphlets were counted as volumes) would benefit from deacidification. At the estimated cost of $4.25 per volume ($2.25 for deacidification and $2.00 for preparation and transport to a local facility), it would take approximately $4.97 million to deacidify all of these volumes. Although it will not be cost-effective for NLM to review volumes individually to determine whether the Library has an obligation to preserve them, some categories of materials may be excluded from NLM's deacidification program based on their subject classification.

Approximately 40,000 volumes are added to the collection annually, and it will cost about $130,000 per year to deacidify these materials as they are received. This figure is based on an estimate of $3.25 per volume, since preparation costs would be reduced if deacidification took place as volumes were received or bound for the collection. NLM's costs for deacidification will be higher if the Library is required to fund all or part of the cost of building a facility.

Beginning in FY 1988, NLM should deacidify 100,000 volumes annually, including all incoming print materials that would benefit from this treatment and making up the remainder from items in the retrospective collection. Depending on the number of new materials acquired on acid-free paper or in non-print form each year, it will take 18-20 years to deacidify the entire retrospective collection that will benefit from this treatment, while also treating all appropriate incoming materials. The cost, depending on the mix of new and old materials, will range from $370,000 to $400,000 annually (in FY 1985 dollars) until all the retrospective collection has been treated. These cost figures are based on the use of an existing facility, and exclude any charges to defray the cost of facility construction. They are probably reasonable estimates of what NLM can expect to pay for use of the LC facility if such use is permitted.

To make certain that mass deacidification services at the required level are available to the Library by 1989, NLM should negotiate with LC for a commitment for NLM use of the mass deacidification facility at Frederick. If sufficient capacity cannot be made available at the LC facility, NLM should work with other research libraries and/or commercial companies to ensure the development of adequate deacidification service for the NLM collection.

C.2. Initiate in FY 1986 a four-year preservation microfilming program for monographs and serial volumes too embrittled to benefit from deacidification.

The survey of the condition of the NLM collection revealed that an estimated 8.8% or 113,000 volumes (or volume equivalents) are brittle. Deacidification will provide relatively little benefit to this material, and disk storage is not yet available for large-scale preservation purposes. These volumes are in danger of crumbling into dust, and microfilming is at present the only available means of dealing with them.

Of the total number of brittle materials, an estimated 104,800 volumes are monographs or serial volumes. Of these an estimated 11,700 volumes have already been microfilmed. Using an average figure of 250 pages per monograph and 500 pages per serial volume, there are 32,118,000 brittle pages that have not been microfilmed. The cost of filming all these pages would be about 3.6 million dollars. These cost estimates are based on figures of $0.15 per exposure (for two printed pages) for creating the original master, $3.50 - $4.50 for the service master and the diazo service copy, and $9.00 per volume for preparation costs and recording preservation data. Some categories of brittle materials will not be filmed, however, because they deal with subjects for which NLM does not assume preservation responsibility or because preservation masters for them already exist. Given the space available for the growth of the collection, NLM has no immediate need to dispose of originals after they are microfilmed. The Preservation Section should be charged, however, with the responsibility for developing specific guidelines covering the retention or disposal of items for which preservation copies have been made.

Filming services are readily available from commercial companies or through an interagency agreement with LC. NLM can also obtain contract support for preparation of materials for filming, similar to the binding preparation services now purchased on contract.

Using contract support for preparation and an outside filmer, NLM should microfilm all brittle monographs and serial volumes in subjects it collects at the comprehensive or research level during FY 1986 - FY 1989. Expenditures for this program should be phased as follows: $600,000 in FY 1986; $1 million per year in FY 1987 through FY 1989.

The Library should assume that microfilming any post-1906 brittle materials in order to preserve them represents a "fair use" of the materials.

Treatment of brittle pamphlets and theses should be deferred pending resolution of the more serious problem of how the Library is to provide bibliographic control for these items.

In 1988/89, NLM should reassess any further use of preservation microfilming based on the results of research in techniques for strengthening paper and the preservation use of mass disk storage. Previously microfilmed images can be transferred to disk if this seems advisable at a later date.

C.3. Expand efforts to preserve items in the special historical collections.

In FY 1985, a total of $235,195 was allocated to preservation of rare books, historical films and modern manuscripts. Of this amount, approximately $115,000 was included in the original FY 1985 operating budget; the remainder was added when funds became available during the year, based on preliminary recommendations from the Preservation Planning Team.

To provide preservation treatment to untreated rare books currently in the NLM collection will require an estimated $362,000 in addition to FY 1985 expenditures. An additional $539,000 will be needed for making preservation and service copies of the historical films. Accurate cost estimates for preserving the entire collection of modern manuscripts are not yet available. A variety of techniques will be applied to these materials, i.e.,hand rebinding and deacidification, microfilming, and possibly strengthening of brittle paper, when this technique becomes available. As mentioned previously, a consultant will be engaged to advise on preservation of the prints and photographs collections. Cost figures will be based on the consultant's report.

Although exact cost figures are not yet available for full preservation of all elements of these collections, NLM should allocate at least $200,000 per year to preservation of special collections for the five-year period from FY 1986 - FY 1990. In 1988/89, NLM should be in a position to estimate the level of funding required for continuing maintenance and treatment of new acquisitions for these special collections.

D. CONTINUE RESEARCH ON THE PRESERVATION CHARACTERISTICS OF OPTICAL DISKS.

Optical disk storage has great promise as a preservation medium. At a minimum, disk storage probably will be the preservation medium of choice for materials published in machine-readable form. Due to its superior use characteristics, it also has strong advantages for printed materials, particularly those that are likely to be used steadily over a long period of time.

Because of the great potential of optical disk as a preservation medium, NLM should continue to contribute to the development of knowledge about the preservation characteristics of this technology. The prototype Electronic Document Storage and Retrieval (EDSR) system developed in the Lister Hill Center should be used as a laboratory test bed for relevant research projects. LHNCBC budget plans for the next few years include appropriate funding for this activity. To ensure that the greatest amount of useful information is obtained in the shortest time frame, NLM's research efforts in optical disk technology should be closely coordinated with those of the Library of Congress, the National Archives, the National Bureau of Standards, and other interested institutions. In a preliminary meeting with NLM's Preservation Planning Team, LC staff expressed interest in cooperative research efforts.

E. ENCOURAGE PUBLICATION IN ARCHIVAL FORMATS

Publication of the scholarly literature on acid-free paper or in other archival formats will lessen the necessity for large-scale treatment of the prospective literature. To this end, NLM should launch a campaign to convince biomedical editors, societies, and publishers of the benefits of publication in archival formats. This campaign should involve a combination of direct appeals by NLM and cooperative efforts with other national libraries and library associations.

F. IMPROVE CONDITIONS FOR STORAGE AND USE OF THE NLM COLLECTION.

Proper storage and handling of library materials will extend their life. An examination of storage and use conditions at NLM has revealed that in general NLM's collection is stored in a benign environment and is handled with reasonable care. Steps should be taken, however, to ensure that this generally favorable situation continues and that specific problems are corrected. In addition to the corrective measures that were initiated during the course of the preservation planning process, the following actions should be taken:

F.1. Continue monitoring temperature and humidity levels; meet regularly with the NIH building engineer to review data collected and request any necessary adjustments.

The Library's system for controlling temperature and humidity is a good one, and the underground position of the stack levels helps prevent rapid or extreme fluctuations in these factors. Periodic adjustments to the system are necessary, however, to ensure that appropriate conditions are maintained. To assist in maintaining a good environment, the monitoring equipment installed during the environmental survey should remain in place, and readings should be taken weekly. Data collected should be reviewed periodically with the NIH building engineer so any necessary corrective action can be taken promptly. As a member of the Task Force on Environmental Conditions, Mr. Herbert Crigger, the NIH engineer currently assigned to the Library building, has become aware of NLM's special environmental requirements and has been extremely willing to make adjustments to the Library's heating and air conditioning system. It is in NLM's best interest to continue this productive working arrangement.

F.2. Ask the NIH Division of Engineering Services to assess the feasibility and cost of retrofitting a chemical filtration system to the existing heating and air conditioning system to remove sulfur dioxide and nitrogen oxides from the Library's air.

The amount of sulfur dioxide and nitrogen oxides in the air of the Library building is well within the acceptable range for humans, but exceeds the standards for storage of Library materials. Sulfur dioxide is generally considered to be more harmful to materials than nitrogen oxides. LC's filtration system for the Madison Building removes sulfur dioxide, but not nitrogen oxides.

Although cost figures vary considerably depending on building size and the existing heating and cooling system, it may well be possible to put a chemical filtration system in the NLM Library building at an affordable cost. If the NIH Division of Engineering Services finds that such an improvement is possible, NLM should have the system installed.

F.3. Investigate the replacement of the photocopiers in use in the Library by machines with less potential for damage to library materials.

The air quality survey showed that ozone levels in the photocopier room adjacent to the Reading Room exceed the standard for an acceptable environment for library materials. Although high ozone levels were not noted in the B1 stack area (probably due to the larger air space there), the photocopiers in heavy use on the B1 level are of same type used by Reading Room patrons. These machines require bound volumes to be opened flat during photocopying. The machines on the B1 level are rented by the Library; the coin-operated copiers available to Reading Room patrons are owned by a commercial firm which is also responsible for their operation. NLM should investigate alternative arrangements that will have a more benign effect on the environment and on the bindings of printed library materials.

F.4. Establish a regular schedule for cleaning the NLM collection.

Steps already taken to have the stack floors cleaned more frequently should reduce the build up of dust and dirt on the collection. NLM should monitor cleaning of the stack areas to ensure that it is occurring as scheduled. The Library should also arrange for the materials themselves to be cleaned and dusted periodically through a purchase order or contract arrangement. The heavily used B1 serial collection should be cleaned every three years; the B2 and B3 levels every five years. Approximate cost will be $10,000 per cleaning for the B1 collection and $50,000 for the combined B2 and B3 collections.

F.5. Develop a new long-range storage plan for the NLM collection.

The existing plan for the storage of the NLM collection provides for adequate storage of the projected acquisitions of the Library through the year 2000. This plan should be reviewed and revised in light of NLM's new preservation strategy. Issues that must be addressed include: the need for additional compact shelving, the amount of compact shelving the NLM building can accommodate, remote or onsite storage for NLM's expanding collection of microfilm masters, the number of materials that will be retained both in the original and preservation copies, and facilities for storage of disks and other machine-readable formats.

F.6. Develop an ongoing training program in safe materials handling for all NLM staff who process or use items in the collection.

All new employees who will handle items in the collection should receive instruction in materials handling when they join the staff. Regular update and refresher sessions should be held for experienced staff. A number of print and audiovisual aids covering recommended handling practices are available, reducing the need for development of inhouse training materials, but specific internal instructions should be developed by appropriate units. Employee performance standards should include reference to safe handling of materials, if appropriate.

F.7. Develop an awareness campaign for Library users describing the importance of safe handling to the preservation of the NLM collection.

Most damage to library materials is caused by simple ignorance or carelessness, not deliberate mutilation. Formal instruction for NLM patrons is not feasible; however, an effort can and should be made to alert patrons to proper handling procedures and the effects of mishandling and abuse. A set of instructional posters, signs and notices should be acquired or developed and distributed appropriately, both onsite and with outgoing interlibrary loans.

G. INITIATE AND PARTICIPATE IN COOPERATIVE PROGRAMS FOR THE PRESERVATION OF THE BIOMEDICAL LITERATURE.

Although NLM's first priority is the preservation of its own collection of materials collected at the comprehensive and research levels, it also has an obligation to engage in cooperative activities that will ensure

the preservation of materials pertinent to medicine held by other libraries and will contribute to a national preservation program. Key elements for a North American preservation program are in place or on the drawing board. These include leadership foci in the Council for Library Resources (CLR), the Research Libraries Group (RLG), the Association of Research Libraries (ARL), and the Library of Congress (LC); a growing body of standards related to preservation; increased funding for preservation from organizations such as the National Endowment for the Humanities; and a growing consensus that the magnitude of the problem demands a cooperative solution. While the emerging national program provides an infrastructure in which to fit the preservation of the biomedical literature, it does not presently address coverage of this subject area. NLM must assume the responsibility for the development of a plan to fill the gap. There are four major areas of opportunity in which NLM can initiate or participate in cooperative programs:
(1) research, which was addressed previously in this report;
(2) actual preservation of the literature; (3) ensuring access to preserved materials, and (4) education for preservation. Specific steps NLM should undertake are:

G.1. Establish Liaisons to Other Preservation Efforts.

NLM should move as expeditiously as possible to establish formal preservation liaisons with the other national libraries and with other major national preservation programs. There is little or no cost associated with such liaisons, and the payoff is potentially high. At a minimum, regular sharing of information about preservation programs may suggest fruitful program opportunities and may reduce duplication of effort.

Recently NLM, LC, and NAL have agreed on primary areas of responsibility for the acquisition of certain library materials in order to reduce the areas of collection overlap. It is important that these discussions continue, and that the national libraries also turn their attention to cooperative programs directed specifically toward preservation.

G.2. Work to Resolve Copyright Issues Related to Preservation of Archival Materials.

NLM must continue to pursue in concert with the national libraries and other professional library associations and organizations the resolution of copyright issues related to preservation, particularly as they relate to storage on disk and other readily accessible media. The goal must be to remove barriers to preservation of the literature while assuring due attention to the rights of publishers and authors.

G.3. Work with the RML Network and Other Library Groups to Develop a National Preservation Program for the Biomedical Literature.

Preservation of NLM's collection alone will not ensure that the needs of future health professionals and medical historians are adequately met. In-depth collections in specialized subject areas and numerous unique titles not found at NLM exist in important health science library collections throughout the country. NLM does not and cannot collect comprehensively many biomedical materials published at the regional, state, and local levels. In addition, it is important to preserve more than one copy of significant materials to avoid their loss through a local disaster.

Plans for the next five years of the RML network include the development of a national preservation plan for the biomedical literature. In developing this plan, NLM and network libraries should collaborate with scholarly societies in establishing priorities for preservation. Once data are gathered on collections in each region and a suitable plan of action outlined, NLM should make some funds available for actual preservation of significant materials in other collections. NLM funds should be used as seed money or to supplement local resources.

G.4. Distribute Information About Materials Which NLM Has Preserved or Intends to Preserve.

In order to avoid wasteful duplication and to promote cooperative planning, it is essential that NLM provide access to information about the material which it has already preserved and which it plans to preserve. NLM should ensure that the MEDLARS III system design and file structures can accommodate display and distribution of preservation data. In addition NLM should work to promote cost-effective mechanisms for the transfer of data about what NLM is preserving to major reservoirs of preservation information.

G.5. Develop a Policy for Access to Preserved Materials.

As a follow-up to the work of the Preservation Planning Team, a committee should be appointed to develop an NLM policy statement describing the terms and conditions of access to the Library's preserved materials. The policy should cover onsite patron use, interlibrary loan, and duplication of preservation copies in whole in part for or by individuals, other libraries, or commercial institutions. In some cases it may be advisable to provide the originals of items for which preservation copies have been made.

G.6. Promote an Awareness of Preservation Issues Among Health Science Libraries and Broaden Their Access to Preservation Information.

NLM should work with the Medical Library Association, the RML network, and other appropriate groups to promote the awareness of preservation issues among health science librarians and medical historians and to broaden their access to preservation information. Although large-scale preservation programs are likely to be needed only at a small number of major health sciences libraries, an increased awareness of preservation issues affecting the health sciences community is desirable at all levels of the network.

H. RE-EVALUATE NLM'S PRESERVATION PROGRAM PERIODICALLY

Like other NLM programs, the preservation operation will be monitored through regular reporting mechanisms and the program review that accompanies budget preparation and approval. Given the new emphasis to be placed on preservation, NLM should also perform a broader review of progress toward the goal of preservation of the biomedical literature at approximately three-year intervals. During this review, NLM should reassess its preservation assumptions and strategies in light of the current and future information needs of the Library's users and developments in preservation technology.

Tables 7 and 8 provide a summary of recommended preservation activities and budget levels for the next five years.

Table 7

SCHEDULE FOR RECOMMENDED STRATEGIES FOR PRESERVATION AT NLM

	FY 1986	FY 1987	FY 1988	FY 1989	FY 1990
A. Modify NLM Board of Regents' policy on preservation	△ △				
B. Establish a new organizational unit to direct NLM's preservation program	△ △				
C. Expand the level of preservation activity at NLM, including:					
negotiate for and begin use of LC or other mass deacidification facility	△ △ Negotiate			△ ——— Use	———→
initiate 4-year microfilming program for severely embrittled materials	△ ———	———	——— |	——— △ Reassess	
expand efforts to preserve items in the special historical collections	△ ———	———	———	———	———→
D. Continue research on the preservation characteristics of optical disks	△ ———	———	——— |	——— Assess Operational Utility	———→
E. Encourage publication in archival formats	△ ———	———	———	———	———→
F. Improve conditions for storage and use of the NLM collection	△ ———	———	———	———	———→
G. Initiate and participate in cooperative programs for preservation of the biomedical literature	△ ———	———	———	———	———→
H. Re-evaluate NLM's preservation program periodically				△ △	

Table 8

MAJOR PRESERVATION PLAN BUDGET ITEMS
(Dollars in Thousands)

	FY 1986	FY 1987	FY 1988	FY 1989	FY 1990
Mass Deacidification	---	---	---	$400	$400
Microfilming	600	1,000	1,000	1,000	
Special Collections Preservation	200	200	200	200	200
TOTAL	$800	$1,200	$1,200	$1,600	$600

The actions proposed will require significant effort by staff throughout the Library and the expenditure of large sums of money. By making a commitment at this level NLM can fulfill its statutory function to preserve the biomedical literature.

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Appendix 1

PRESERVATION AT THE NATIONAL LIBRARY OF MEDICINE

Background Paper

NLM Preservation Planning Team

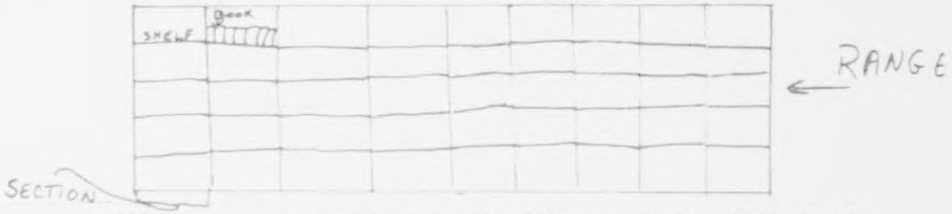
November 1984

Appendix 3

Procedures Used in the Survey of the Physical Condition of the Collection

PHYSICAL CONDITION SURVEY

The books you are to examine in the stacks have been preselected at random. Your tally sheet indicates which range, section, shelf, and book you are to look at. Here is a diagram which explains what is meant by the terms: range, section, shelf and book.



All ranges are numbered in the library stacks, both in the General Collection (A, B, and C levels) and in the History of Medicine Division. A double range has only one number, so for ease in this project, they are subdivided into "A" and "B" halves. "A" is the side to the North or closest to HMD in the General Collection.

The number of the Section is counted from the aisle. Count sections from left to right as you are facing the section. This will ensure that the same section is reached no matter what aisle you may enter the section from.

Count shelves from top to bottom. Count books from left to right. If there is no book that matches the one you are supposed to pull, place a large "X" in the call number area of the tally sheet. When you pull the book you are to examine, first write down the call number with volume and year information. Be as complete as necessary to identify the specific volume. You may shorten the title.

Examine the book and enter your results following the "Instructions for Examining Paper Media for Physical Condition".

INSTRUCTIONS FOR EXAMINING PAPER MEDIA FOR PHYSICAL CONDITION

A survey of selected titles will be performed to collect data on their physical condition. Volumes to be examined will be randomly selected. The information on the worksheet will lead you to the specific volume to test.

There are two components to the physical condition to be recorded. The first is the fold test for brittleness of paper. The second is the state of the binding and overall condition of the piece.

The fold test is conducted in the following manner. A random page of the volume (chosen from the midpart of the book, not the first or last few pages) is selected and the upper corner tested. Fold, without creasing, the corner forward 135 degrees (almost all the way down), then fold it back in the opposite direction approximately 270 degrees (almost all the way down in the opposite direction), then bring it forward approximately 135 degrees to its original postition. Do not crease. This three-step procedure constitutes "one fold" if the corner remains attached to the page. If the corner breaks off during the first test, it is in "zero fold" condition. If it completes one full test, and breaks during the second, it is in "one fold" condition, etc. . . . Record the number of completed folds. Do not test further than 10 folds.

The condition of the binding and pages will fit into one of the following categories. Record the letter code which best describes the book you are examining.

A. Good binding, no loose pages.
B. Text block intact, sewing tight, but loose from binding.
C. Text block intact, sewing tight, but out of binding.
D. Textblock intact, sewing tight, binding badly damaged, red rot, etc.
E. Good binding, but torn pages.
F. Unbound issue.
G. Text blockintact, but loose from binding andtorn pages.
H. Text block intact, but out of binding and torn pages.
I. Text block intact, but binding damaged and torn pages.
J. Unbound issue with torn pages.
K. Environmental damage, including insects, water, mold, etc. (Give these to Carol Unger immediately after recording so that further damage or contaminatation can be prevented.)
L. Bound, text block and sewing coming apart.

Condition Grades for Manuscript Materials

A. Container and Manuscripts in good condition.

B. Container damage, including torn boxes and folders.

C. Manuscripts have frayed edges or tears.

D. Container damage, and manuscripts have frayed edges or tears.

E. Manuscripts have rusting metal clips, staples, etc. present.

F. Container damage, and manuscripts havd rusting metal clips, staples, etc, present.

G. Manuscripts have frayed edges or tears, and rusting metal clips, staples, etc. are present.

H. Container damage, and manuscripts have frayed edges and tears, and rusting metal clips, staples, etc. are present.

I. Manuscripts are badly yellowed and/or foxed (over 30% of item).

J. Enviromental damage to manuscripts, including insects, water, mold, etc.

Summary Categories for Physical Condition

Bound Paper Media

A = Good

B,C,D,L = Binding Damaged

E,G,H,I = Pages Torn

F,J = Unbound

K = Environmental Damage

Unbound Manuscripts

A = Good

B,C,D,E,F = Moderate

G,H,I,J = Poor/Environmental Damage

INSTRUCTIONS FOR SAMPLING
16MM FILM FOR PHYSICAL CONDITION

There are eight (8) components to the physical condition to be recorded. The material to be examined will be randomly selected. The information on the worksheet will lead you to the specific item to be examined. The conditions should fit into one of the following categories. Record the letter code which best describes the item being examined.

COMPONENT		DESCRIPTION
1	A)	GOOD - No splices or obvious scratches, or pulled sprockets
	B)	FAIR - Maximum of four (4) splices, and minimal scratching
	C)	POOR - Excess of four (4) splices, heavily scratched
	D)	SHRUNKEN - Distance between sprockets shortened, (use guage)
	E)	BRITTLE - Use end fold test (maximum of 10 folds of 180°)
	F)	MISSING - Not on shelf
2	A)	NORMAL COLOR - Realistic flesh color or recognizable item color
	B)	OFF-COLOR - Unrealistic flesh color (Blue, green, etc.) of recognizable item color
	C)	FADED OVERALL - Everything same color
3	A)	GOOD - Clear, sharp, black & white images
	B)	POOR - "Washed-out" images or extremely dark images
4	A)	GOOD - Clear, distinct voice sounds
	B)	DISTORTED - Garbled voice sounds
	C)	N/A - Not applicable (slient)
5	A)	COMPLETE - Correct number films (Part I, Part II, etc.)
	B)	INCOMPLETE - Missing film parts from the title
	C)	MISSING - Not on shelf
6	A)	GOOD - Beeper in place and no adhesive leakage
	B)	OOZING - Beeper in place but adhesive leaking
	C)	MISSING - No Beeper applied or was removed
7	A)	GOOD - Label in place, legible
	B)	POOR - Label defaced, illegible
	C)	MISSING - No label visible

8 A) GOOD - Binding tight, no loose or missing pages
B) POOR - Binding loose, torn and pages missing
C) BRITTLE - Apply print media fold test (10 fold limitation)
D) MISSING - Not with film
E) N/A - Not applicable

INSTRUCTIONS FOR SAMPLING SLIDES & SLIDE/TAPES FOR PHYSICAL CONDITION

There are nine(9) components to the physical condition to be recorded. The material to be examined will be randomly selected. The information work sheet will lead you to the specific item to be examined.

The conditions of the sample should fit into one of the following categories. Record the letter code which best describes the item being examined.

COMPONENT	DESCRIPTION
1	A) GOOD - no physical damage visible D) MISSING - not in kit
2	A) NORMAL COLOR - Realistic flesh color or recognizable item color B) OFF-COLOR - unrealistic flesh color (Blue, green, etc.) or recognizable item color C) FADED OVERALL - Everything same color
3	A) GOOD - No apparent damage visible N/A - Not applicable
4	(Self-explanatory) N/A - Not applicable
5	A) GOOD - Clear distinct voice sound B) DISTORTED - Garbled voice sound C) NO AUDIO - No voice sound recorded D) MISSING - No cassette/s E) N/A - Not applicable
6	A) GOOD - No tears or separation of binder B) FAIR - Clasp does not hold, otherwise binder is all right C) MISSING - Not on shelf
7	A) GOOD - Beeper in place, no adhesive leakage B) OOZING - Beeper in place, adhesive leakage C) MISSING - No beeper applied or was removed
8	A) GOOD - No label adhesive leekage or smearing B) OOZING - Label adhesive leaking, smearing C) MISSING - No label visible
9	A) GOOD - No torn or missing pages B) POOR - Torn and missing pages C) BRITTLE - Apply print media fold test, (10 fold limitation) D) MISSING - Not with cassette/s E) N/A - Not applicable

INSTRUCTIONS FOR SAMPLING FILM STRIPS FOR PHYSICAL CONDITION

There are ten (10) components to the physical condition to be recorded. The material to be examined will be randomly selected. The information worksheet will lead you to the specific item to be examined. The conditions of the sample should fit into one of the following categories. Record the letter code which best describes the item being examined.

COMPONENT	DESCRIPTION
1	A) GOOD - No obviously torn or pulled sprocket holes or scratches B) FAIR - Some pulled sprocket holes, minimal scratches C) POOR - Badly pulled sprocket holes, deeply scratched, and/or multiple splices
2	A) GOOD - Normal flesh color or recognizable item color B) OFF-COLOR - Unrealistic flesh color (green faces, etc.), or recognizable item color C) FADED OVERALL - Everything same color
3	A) GOOD - No physical damage visible B) N/A - Not applicable, not required
4	(Self-explanatory) N/A - Not applicable
5	A) GOOD - Clear, distinct voice sound B) DISTORTED - Garbled voice sound C) NO AUDIO - No voice sound recorded D) MISSING - No cassette E) N/A - Not applicable
6	A) COMPLETE - Correct number of film strips/cassettes in kit B) INCOMPLETE - Film strips/cassettes missing from kit C) MISSING - Not on shelf
7	A) GOOD - No tears of separation of binder B) FAIR - Clasp does not hold or close properly, otherwise it is alright C) MISSING - Not on shelf
8	A) GOOD - Beeper in place, no adhesive leakage B) OOZING - Beeper in place, adhesive leakage C) MISSING - No beeper applied or was removed

A) GOOD - No label adhesive leakage or smearing
9 B) OOZING - Label adhesive leaking, smearing
C) MISSING - No label visible

A) GOOD - Binding tight, no torn, loose, or missing pages
B) POOR - Binding loose, torn and missing pages
10 C) BRITTLE - Apply print media fold test (10 fold limitation)
D) MISSING - Not with kit
E) N/A - Not applicable

INSTRUCTIONS FOR SAMPLING VIDEO TAPE CASSETTES FOR PHYSICAL CONDITION

There are eleven (11) components to the physical condition to be recorded. The material to be examined will be randomly selected. The information worksheet will lead you to the specific item to be examined. The conditions of the sample should fit into one of the cateogries. Record the letter code which best describes the item being examined.

COMPONENT	DESCRIPTION
1	A) GOOD - No apparent damage visible B) DAMAGED - Cracked, screws missing C) MISSING - Not on shelf
2	A) NO - (Self explanatory) B) YES - Note number of video dropouts
3	A) NO - (Self explanatory) B) YES - Note number of audio dropouts
4	A) GOOD - Cassette tape runs smoothly B) ERRATIC - Cassette tape runs noisily C) JAMMED - Cassette tape locked will run
5	A) NORMAL - Realistic flesh color are recognizable item color B) OFF-COLOR - (green faces, etc.)
6	A) NORMAL - Clear, sharp images B) POOR - Weak, washed-out images
7	A) COMPLETE - Correct number of films in kit B) INCOMPLETE - Films and/or cassettes missing from kit C) MISSING - Not on shelf
8	A) GOOD - No tears or separation of binder 9) FAIR - Binder does not close properly, otherwise binder is allright C) MISSING - Not on shelf
9	A) GOOD - Beeper in place, no adhesive leakage B) OOZING - Beeper in place, adhesive leakage C) MISSING - No beeper applied or was removed
10	A) GOOD - No label adhesive leakage or smearing B) OOZING - Label adhesive leaking, smearing C) MISSING - No label visible
11	A) GOOD - Binding tight, no loose or missing pages B) POOR - Binding loose, torn, and pages missing C) BRITTLE - Apply print media fold test (10 fold limitation) D) MISSING - Not with video cassettes E) N/A - Not applicable (not provided)

INSTRUCTIONS FOR SAMPLING AUDIO TAPE CASSETTES FOR PHYSICAL CONDITION

There are eight (8) components to the physical condition to be recorded. The material to be examined will be randomly selected. The information on the worksheet will lead you to the specific item to be examined.

The conditions should fit into one of the following cateogries. Record the letter code which best describes the item being examined.

COMPONENT	DESCRIPTION
1	A) GOOD - No apparant damage visible
	B) CRACKED/WARPED - Cassette shows apparent damage
	C) MISSING - Not on shelf
2	A) GOOD - Cassette tape runs smoothly
	B) ERRATIC - Cassette tape drags
	C) JAMMED - Cassette tape locked will not run
3	A) GOOD - Clear distinct voice sound
	B) DISTORTED - Garbled voice sound
	C) NO AUDIO - No voice sound recorded (blank)
	D) MISSING - Not on shelf
4	A) COMPLETE - Correct number of cassettes in kit
	B) INCOMPLETE - Cassettes missing from kit
	C) MISSING - Not on shelf
5	A) GOOD - No visible damage
	B) FAIR - Torn, or fails to close properly
	C) MISSING - Not on shelf
	D) N/A - Binder not supplied
6	A) GOOD - Beeper in place and no adhesive leakage
	B) OOZING - Beeper in place but adhesive leaking
	C) MISSING - No beeper applied or was removed
7	A) GOOD - Label in place, no adhesive leakage
	B) OOZING - Label in place, adhesive leaking
	C) MISSING - No label visible
8	A) GOOD - Binding tight, no loose or missing pages
	B) POOR - Binding loose, torn and pages missing
	C) BRITTLE - Apply print media fold test, (10 fold limitation)
	D) MISSING - Not with cassette/s
	E) N/A - Not applicable

Appendix 4

553-3-85

Indoor Pollutant Measurements of Sulfur Dioxide, Nitrogen Oxides, and Ozone in the National Library of Medicine

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Introduction

Levels of atmospheric pollutants, specifically sulfur dioxide, nitrogen oxides, and ozone were measured at two locations inside building #38 of the National Library of Medicine between April 8 and April 15, 1985. The locations at which these species were monitored were a stack area on the B2 level and the southeast corner of the main reading area on the B1 level. Ozone also was measured in the photocopy room on the B1 level identified as room 1W-27.

Measurement Plan

Continuous monitoring analyzers were used to sample the air exiting the ventilation system for periods of at least 48 hours at each site. Ambient sulfur dioxide levels were measured with a pulsed fluorescent sulfur dioxide analyzer. Nitrogen oxides, as NO_x (NO_2 + NO), were measured with an oxides of nitrogen analyzer utilizing the photometric detection of chemiluminescent light resulting from the reaction of nitric oxide with ozone. Ambient ozone levels were measured with a microcoulomb ozone sensing instrument.

The signals generated by the three analyzers were continuously recorded on strip chart recorders.

The sampling probe for the nitrogen oxides and sulfur dioxide analyzers was located directly in the path of incoming air exiting the ventilation system at both sites. The sample inlet of the ozone analyzer on the B2 level was positioned to sample air away from the inlet vents. This was done for two reasons. First, to reduce the probability of loss of ozone due to the length of the sampling probe needed to reach the ventilation inlet vents located at ceiling level and second, to include in the sample air surrounding a nearby photocopy machine to determine whether ozone was being generated by the machine. On the B1 level it was possible to sample incoming air for ozone directly in front of a ventilation vent. Measurements of ozone made in the photocopy room were intended only to quantify any ozone produced by the photocopiers.

Calibrations

Calibrations of the sulfur dioxide and nitrogen oxides analyzers were performed on a daily basis with the use of permeation tubes. The permeation devices used in the calibrations were themselves calibrated at NBS. These devices produce low known concentrations of sulfur dioxide or nitrogen dioxide in air by placing the tube of interest in a stream of purified air flowing at a known rate and at a known temperature. The flow of diluent air passed over each tube was measured with a calibrated mass flow meter. The permeation rate of the tubes at the times of calibrations was estimated from the measured temperature dependence of the rate and the temperature at which they were used.

To assign an estimated uncertainty to the concentrations of the generated calibration mixtures, the variations in the measured instrument sensitivities were used. The observed variation of the sensitivity (signal/concentration) for both the sulfur dioxide and nitrogen oxides analyzers was about ± 10 percent relative over the entire monitoring period during which measurements were taken.

The ozone sensitivity of the ozone analyzer was determined at NBS using an ultraviolet adsorption instrument and a standard reference photometer instrument. The signal generated by the analyzer is linearly proportional to the oxidant content of the gas sampled, however its response can be affected by interfering substances common to pollutants present in the atmosphere. For example, sulfur dioxide can interfere thus reducing the ozone-caused signal. Though it is difficult to accurately quantitate ozone levels, the values recorded by the analyzer show relative differences in concentrations of ozone in the air sampled.

Data Presentation

The concentration levels found for sulfur dioxide, nitrogen oxides, and ozone are summarized in Tables 1-9. The concentrations are given in parts per billion (ppb) by mole. These values indicate the levels measured at the approximate times indicated, and are not hourly averages.

Figures 1-9 contain plots of the sulfur dioxide and nitrogen oxides data taken from Tables 1-9 respectively.

Figures 10 and 11 represent plots of ozone measured based on the appropiate data tables.

Daily temperature and relative humidity measurements were made at the library within the vicinity of the monitoring sites. These data are listed in Table 10.

Results: Nitrogen Oxides

With the major contribution of nitrogen oxides being that generated by the automobile engine, it can be expected that increases in levels would occur during high densities of traffic (e.g. a.m. and p.m. rush hours). Careful examination of several of the plots show an increase in levels which can be correlated with traffic patterns. For example, figure 1 shows a nitrogen oxides peak between the hours of 4:00 p.m. and 7:00 p.m., the evening rush hours.

Figure 6 shows a relatively large nitrogen oxides peak. The highest concentration recorded was 208 ppb and was measured in the main reading area on the B1 level. On this particular day, weather information obtained from the Washington National Airport indicated the wind direction as being from the south-southeast at 8 mph. This would correspond with an air movement across Wisconsin Avenue picking up quantities of "traffic gases" and moving them directly toward the library building. When the wind is from other directions, north or west, considerable dilution of the traffic gases from other major traffic arteries would occur and the maximum in the nitrogen oxides measurements during rush hour periods would be reduced or non-existent.

Results: Sulfur Dioxide

From the data obtained, the most significant amount of sulfur dioxide measured was from the inlet vent located on the B2 level on April 9, 1985. The wind direction during the day was from the west at 15 mph. Such a wind direction would carry effluent from the power plant on the grounds at NIH and conceivably could be the source of the increased sulfur dioxide.

In general, the maximum values measured on the B2 level are higher than the maximum measured on the B1 level. However, the background concentrations as indicated by the minimum levels are the same indicating that the source of the higher concentrations observed on the B2 level is probably external and does not originate within the B2 level or its associated ventilation system.

Results: Ozone

No significant amounts of ozone were detected on the B2 level except for a period of about 1 hour on April 9, 1985, peaking at about 11:30 a.m. At this time, the photocopy machine was in constant use. A sudden increase in ozone from 1 to 8 ppb occurred at that time.

Higher levels were recorded on the B1 level due to the greater accessibility to the inlet vent.

The Council of Government reported an air quality index of 30 for ozone on April 9, 35 on April 10, and 40 on April 11, 1985. Figure 10 represents ozone measured on April 11, 1985, during the day which the index was 40.

The most significant amount of ozone in the library was measured inside the photocopy room IW-27 which contained five photocopy machines that were in frequent use. Tables 6-9 contain concentrations measured of ozone determined in the photocopying room IW-27 (marked with an asterisk). Figure 11 depicts ozone levels measured inside room IW-27 during April 13, 1985. This figure shows that the ozone level increased at approximately 9:00 a.m. and decreased at approximately 5:00 p.m., which correlates with the opening and closing hours of the library.

Conclusions

The concentrations of the three pollutants measured and the variations noted follow the general pattern observed in a previous study [1] for a large building in which the ventilation system does not act as a scrubber or purifier. The minimum values for each pollutant are approximately the same as was found in the previous study. The character of the concentration changes during an extended sampling period, 24 hours, and the height of the daily maximums were not as comparable but the difference in nature of the locations of the building could easily explain the difference. A conclusion to be drawn from this data is that in this particular building the interior atmosphere will reflect almost without change the external atmosphere except in those areas where, in this case ozone, is being internally generated.

The characteristic odor of ozone detected along with the results obtained indicate that significant levels are being generated and accumulated within room IW-27 by the photocopy machines during times when the machines are in frequent use. It should be noted that greater accumulations of ozone within room IW-27 than those measured could result in a potential health hazzard [2] due to the low recommended "permissible exposure limits" established for ozone.

References

[1] Hughes, E., and Myers, R., Measurement of the Concentration of Sulfur Dioxide, Nitrogen Oxides, and Ozone in the National Archives Building, NBSIR 83-2767 , Natl. Bureau of Standards, Gaithersburg, Md.

[2] Little, A., NIOSH/OSHA Pocket Guide to Chemical Hazards, Aug. 1980.

Measurements of Sulfur Dioxide, Nitrogen Oxides, and Ozone in the National Library of Medicine

Table 1

Concentrations listed are in parts per billion (ppb) by mole.

Sampling site	Date	Time	Sulfur dioxide	Nitrogen oxides	Ozone
B2 level	4/8/85	1200	---	65	---
B2 level	4/8/85	1300	---	38	---
B2 level	4/8/85	1400	---	34	---
B2 level	4/8/85	1500	---	46	---
B2 level	4/8/85	1600	4	38	1
B2 level	4/8/85	1700	21	65	1
B2 level	4/8/85	1800	24	65	1
B2 level	4/8/85	1900	7	42	1
B2 level	4/8/85	2000	2	34	2
B2 level	4/8/85	2100	2	27	2
B2 level	4/8/85	2200	2	34	1
B2 level	4/8/85	2300	2	38	1
B2 level	4/8/85	2400	3	46	1
		Minimum	2	27	1
		Maximum	24	65	2

--- No measurements were made at this time.

Measurements of Sulfur Dioxide, Nitrogen Oxides, and Ozone in the National Library of Medicine

Table 2

Concentrations listed are in parts per billion (ppb) by mole.

Sampling site	Date	Time	Sulfur dioxide	Nitrogen oxides	Ozone
B2 level	4/9/85	0100	3	46	1
B2 level	4/9/85	0200	2	38	1
B2 level	4/9/85	0300	2	27	2
B2 level	4/9/85	0400	2	27	2
B2 level	4/9/85	0500	1	27	1
B2 level	4/9/85	0600	1	27	1
B2 level	4/9/85	0700	2	27	1
B2 level	4/9/85	0800	2	30	2
B2 level	4/9/85	0900	4	34	1
B2 level	4/9/85	1000	36	57	1
B2 level	4/9/85	1100	---	49	1
B2 level	4/9/85	1200	7	42	2
B2 level	4/9/85	1300	---	57	1
B2 level	4/9/85	1400	12	49	2
B2 level	4/9/85	1500	22	53	1
B2 level	4/9/85	1600	22	34	1
B2 level	4/9/85	1700	22	46	1
B2 level	4/9/85	1800	47	42	1
B2 level	4/9/85	1900	36	65	1
B2 level	4/9/85	2000	49	65	1
B2 level	4/9/85	2100	44	57	1
B2 level	4/9/85	2200	30	57	1
B2 level	4/9/85	2300	26	53	1
B2 level	4/9/85	2400	22	49	1
		Minimum	1	27	1
		Maximum	49	65	2

--- No measurements were made at this time.

Measurements of Sulfur Dioxide, Nitrogen Oxides, and Ozone in the National Library of Medicine

Table 3

Concentrations listed are in parts per billion (ppb) by mole.

Sampling site	Date	Time	Sulfur dioxide	Nitrogen oxides	Ozone
B2 level	4/10/85	0100	6	30	1
B2 level	4/10/85	0200	20	30	1
B2 level	4/10/85	0300	3	23	1
B2 level	4/10/85	0400	14	27	1
B2 level	4/10/85	0500	4	27	1
B2 level	4/10/85	0600	4	27	1
B2 level	4/10/85	0700	2	30	1
B2 level	4/10/85	0800	18	49	1
B2 level	4/10/85	0900	10	42	1
B2 level	4/10/85	1000	---	---	1
		Minimum	2	23	1
		Maximum	20	49	1

--- No measurements were made at this time.

Measurements of Sulfur Dioxide, Nitrogen Oxides, and Ozone in the National Library of Medicine

Table 4

Concentrations listed are in parts per billion (ppb) by mole.

Sampling site	Date	Time	Sulfur dioxide	Nitrogen oxides	Ozone
B1 level	4/10/85	1500	---	---	11
B1 level	4/10/85	1600	3	59	14
B1 level	4/10/85	1700	2	43	13
B1 level	4/10/85	1800	2	37	14
B1 level	4/10/85	1900	3	37	10
B1 level	4/10/85	2000	5	46	2
B1 level	4/10/85	2100	5	59	2
B1 level	4/10/85	2200	5	43	4
B1 level	4/10/85	2300	3	37	6
B1 level	4/10/85	2400	2	34	7
		Minimum	2	34	2
		Maximum	5	59	14

--- No measurements were made at this time.

Measurements of Sulfur Dioxide, Nitrogen Oxides, and Ozone in the National Library of Medicine

Table 5

Concentrations listed are in parts per billion (ppb) by mole.

Sampling site	Date	Time	Sulfur dioxide	Nitrogen oxides	Ozone
B1 level	4/11/85	0100	2	28	12
B1 level	4/11/85	0200	2	28	12
B1 level	4/11/85	0300	1	28	12
B1 level	4/11/85	0400	2	31	13
B1 level	4/11/85	0500	1	31	11
B1 level	4/11/85	0600	2	28	10
B1 level	4/11/85	0700	2	28	8
B1 level	4/11/85	0800	2	37	4
B1 level	4/11/85	0900	2	46	3
B1 level	4/11/85	1000	2	46	---
B1 level	4/11/85	1100	---	43	11
B1 level	4/11/85	1200	---	---	13
B1 level	4/11/85	1300	19	46	13
B1 level	4/11/85	1400	6	43	16
B1 level	4/11/85	1500	5	46	17
B1 level	4/11/85	1600	6	46	16
B1 level	4/11/85	1700	8	53	13
B1 level	4/11/85	1800	8	37	17
B1 level	4/11/85	1900	4	37	12
B1 level	4/11/85	2000	5	43	3
B1 level	4/11/85	2100	5	140	2
B1 level	4/11/85	2200	4	71	2
B1 level	4/11/85	2300	4	59	4
B1 level	4/11/85	2400	4	53	4
		Minimum	1	28	2
		Maximum	19	140	17

--- No measurements were made at this time.

Measurements of Sulfur Dioxide, Nitrogen Oxides, and Ozone in the National Library of Medicine

Table 6

Concentrations listed are in parts per billion (ppb) by mole.

Sampling site	Date	Time	Sulfur dioxide	Nitrogen oxides	Ozone
B1 level	4/12/85	0100	4	40	2
B1 level	4/12/85	0200	4	46	2
B1 level	4/12/85	0300	3	81	1
B1 level	4/12/85	0400	3	155	2
B1 level	4/12/85	0500	2	177	2
B1 level	4/12/85	0600	4	152	2
B1 level	4/12/85	0700	4	180	2
B1 level	4/12/85	0800	6	208	2
B1 level	4/12/85	0900	11	130	2
B1 level	4/12/85	1000	15	93	2
B1 level	4/12/85	1100	11	71	3
B1 level	4/12/85	1200	9	53	5
B1 level	4/12/85	1300	---	---	7
B1 level	4/12/85	1400	---	---	40 #
B1 level	4/12/85	1500	3	34	29 #
B1 level	4/12/85	1600	2	31	27 #
B1 level	4/12/85	1700	3	31	40 #
B1 level	4/12/85	1800	4	46	52 #
B1 level	4/12/85	1900	4	56	8 #
B1 level	4/12/85	2000	3	53	6 #
B1 level	4/12/85	2100	11	56	5 #
B1 level	4/12/85	2200	6	50	6 #
B1 level	4/12/85	2300	8	34	7 #
B1 level	4/12/85	2400	4	31	9 #
		Minimum	2	31	1
		Maximum	15	208	52

--- No measurements were made at this time.

Ozone measurements were made in the photocopy room located in room 1N-27.

Measurements of Sulfur Dioxide, Nitrogen Oxides,
and Ozone in the National Library of Medicine

Table 7

Concentrations listed are in parts per billion (ppb) by mole.

Sampling site	Date	Time	Sulfur dioxide	Nitrogen oxides	Ozone
B1 level	4/13/85	0100	2	28	10 #
B1 level	4/13/85	0200	2	25	10 #
B1 level	4/13/85	0300	2	28	8 #
B1 level	4/13/85	0400	3	34	3 #
B1 level	4/13/85	0500	2	50	3 #
B1 level	4/13/85	0600	2	46	4 #
B1 level	4/13/85	0700	3	46	4 #
B1 level	4/13/85	0800	4	43	5 #
B1 level	4/13/85	0900	2	31	9 #
B1 level	4/13/85	1000	2	31	26 #
B1 level	4/13/85	1100	2	31	29 #
B1 level	4/13/85	1200	2	34	54 #
B1 level	4/13/85	1300	2	28	38 #
B1 level	4/13/85	1400	2	34	48 #
B1 level	4/13/85	1500	2	37	62 #
B1 level	4/13/85	1600	2	34	60 #
B1 level	4/13/85	1700	2	31	53 #
B1 level	4/13/85	1800	1	31	14 #
B1 level	4/13/85	1900	1	34	12 #
B1 level	4/13/85	2000	1	31	12 #
B1 level	4/13/85	2100	1	31	10 #
B1 level	4/13/85	2200	1	28	11 #
B1 level	4/13/85	2300	0	28	8 #
B1 level	4/13/85	2400	0	28	7 #
		Minimum	0	25	3
		Maximum	4	50	62

--- No measurements were made at this time.

Ozone measurements were made in the photocopy room located in room 1N-27.

Measurements of Sulfur Dioxide, Nitrogen Oxides, and Ozone in the National Library of Medicine

Table 8

Concentrations listed are in parts per billion (ppb) by mole.

Sampling site	Date	Time	Sulfur dioxide	Nitrogen oxides	Ozone
B1 level	4/14/85	0100	1	25	7 #
B1 level	4/14/85	0200	3	25	5 #
B1 level	4/14/85	0300	3	25	4 #
B1 level	4/14/85	0400	4	25	3 #
B1 level	4/14/85	0500	5	25	2 #
B1 level	4/14/85	0600	6	25	2 #
B1 level	4/14/85	0700	6	31	2 #
B1 level	4/14/85	0800	7	31	2 #
B1 level	4/14/85	0900	7	31	2 #
B1 level	4/14/85	1000	6	31	3 #
B1 level	4/14/85	1100	6	34	3 #
B1 level	4/14/85	1200	6	31	5 #
B1 level	4/14/85	1300	3	28	10 #
B1 level	4/14/85	1400	2	28	10 #
B1 level	4/14/85	1500	2	25	10 #
B1 level	4/14/85	1600	2	25	10 #
B1 level	4/14/85	1700	2	25	10 #
B1 level	4/14/85	1800	2	25	9 #
B1 level	4/14/85	1900	2	28	9 #
B1 level	4/14/85	2000	2	28	8 #
B1 level	4/14/85	2100	2	40	5 #
B1 level	4/14/85	2200	2	43	4 #
B1 level	4/14/85	2300	1	34	5 #
B1 level	4/14/85	2400	2	31	4 #
		Minimum	1	25	2
		Maximum	7	43	10

--- No measurements were made at this time.

Ozone measurements were made in the photocopy room located in room 1N-27.

Measurements of Sulfur Dioxide, Nitrogen Oxides, and Ozone in the National Library of Medicine

Table 9

Concentrations listed are in parts per billion (ppb) by mole.

Sampling site	Date	Time	Sulfur dioxide	Nitrogen oxides	Ozone
B1 level	4/15/85	0100	2	28	5 #
B1 level	4/15/85	0200	2	22	7 #
B1 level	4/15/85	0300	2	40	8 #
B1 level	4/15/85	0400	1	34	8 #
B1 level	4/15/85	0500	2	22	8 #
B1 level	4/15/85	0600	3	22	6 #
B1 level	4/15/85	0700	2	31	3 #
B1 level	4/15/85	0800	5	50	2 #
B1 level	4/15/85	0900	---	---	3 #
B1 level	4/15/85	1000	---	---	4 #
B1 level	4/15/85	1100	---	---	30 #
		Minimum	1	22	2
		Maximum	5	50	30

--- No measurements were made at this time.

Ozone measurements were made in the photocopy room located in room IW-27.

Temperature and Relative Humidity Measurements

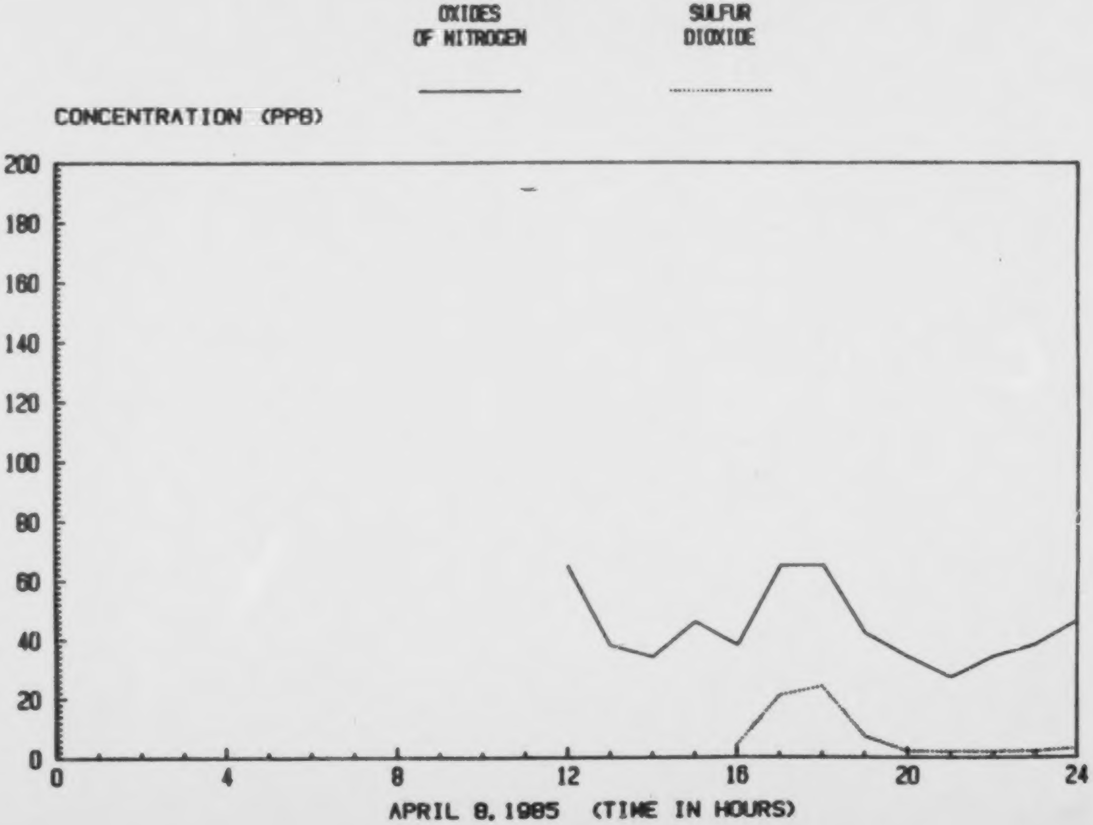
Table 10

Temperatures listed are in degrees celsius.

Sampling site	Date	Time	Temperature	Relative humidity
B2 level	4/08/85	1455	22.0	36 %
B2 level	4/09/85	0930	22.1	36 %
B2 level	4/09/85	1155	22.0	36 %
B2 level	4/10/85	1000	22.0	29 %
		Average temperature	22.0	
B1 level	4/10/85	1510	22.7	29 %
B1 level	4/11/85	1055	22.8	34 %
B1 level	4/12/85	1300	23.2	45 %
B1 level	4/15/85	1055	23.3	56 %
		Average temperature	23.0	

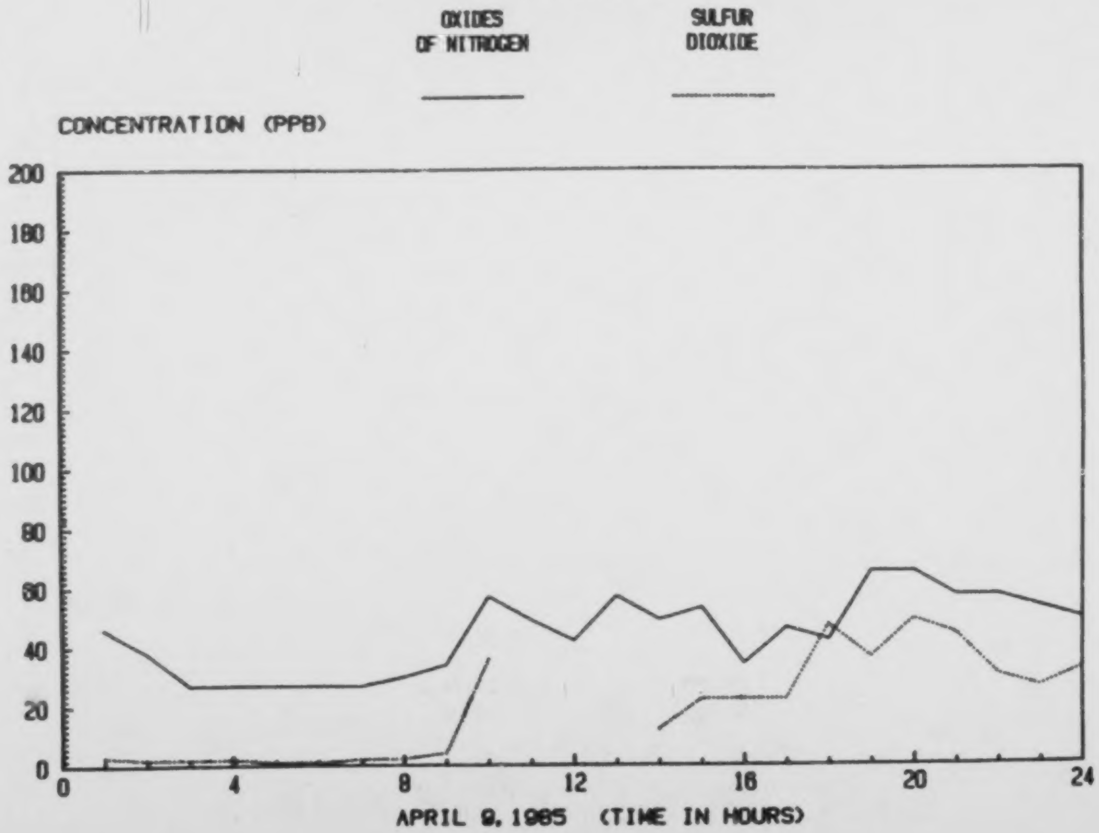
INDOOR POLLUTANT MEASUREMENTS

FIGURE 1.



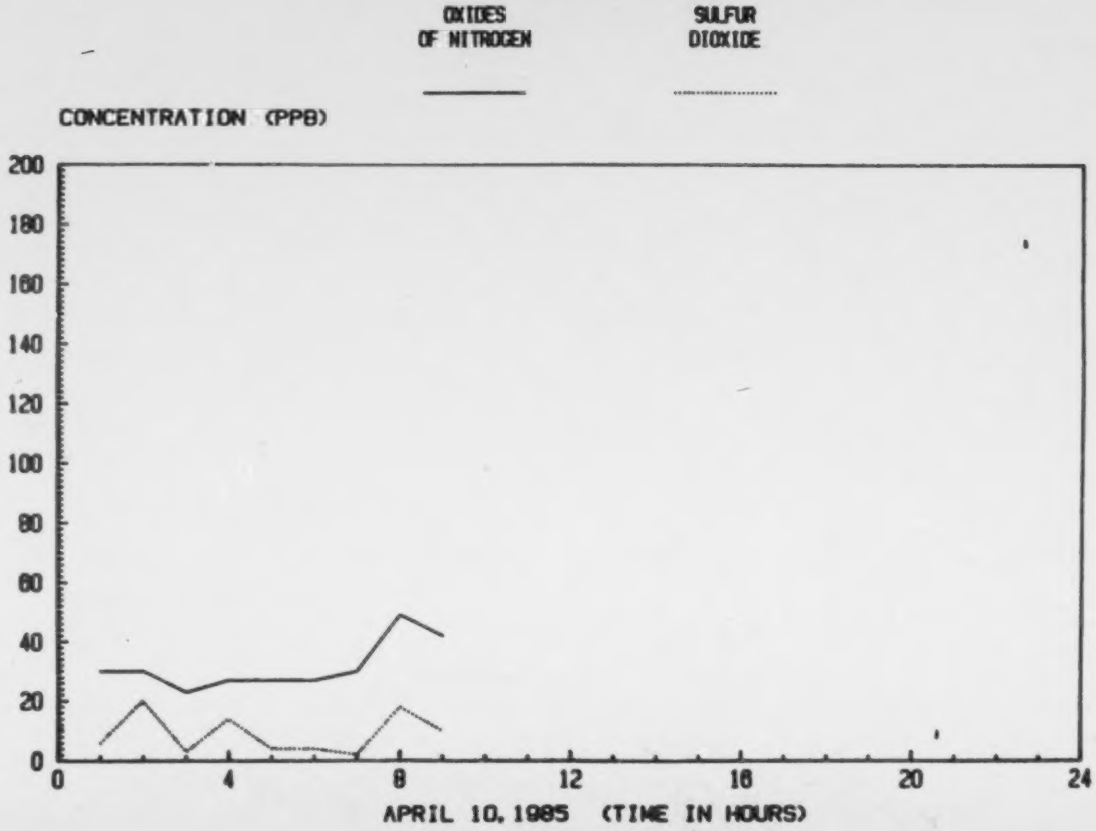
INDOOR POLLUTANT MEASUREMENTS

FIGURE 2.



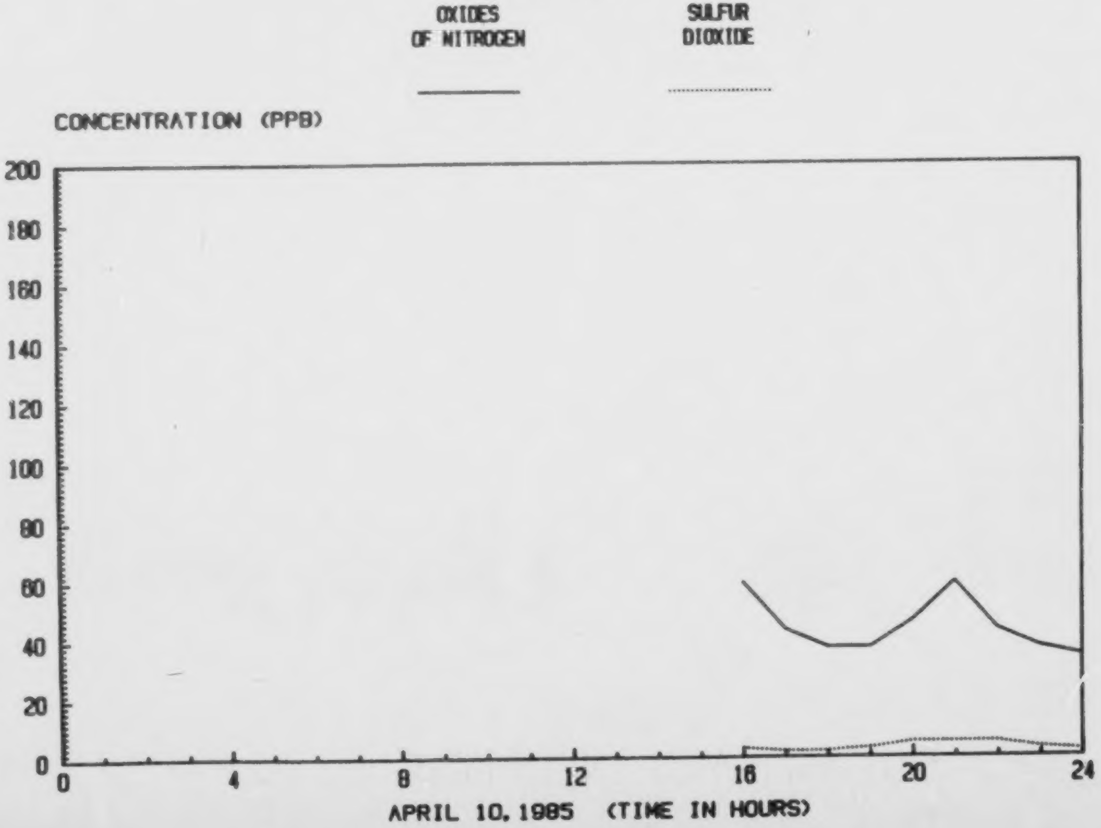
INDOOR POLLUTANT MEASUREMENTS

FIGURE 3.



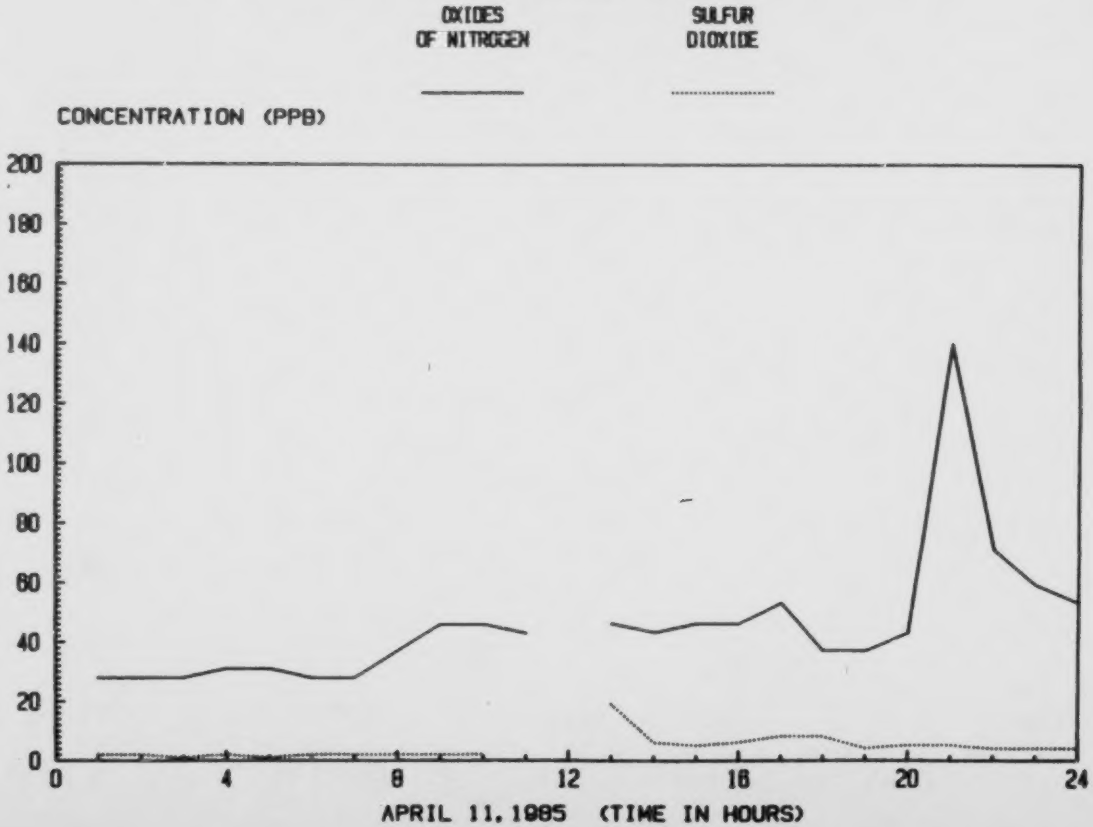
INDOOR POLLUTANT MEASUREMENTS

FIGURE 4.



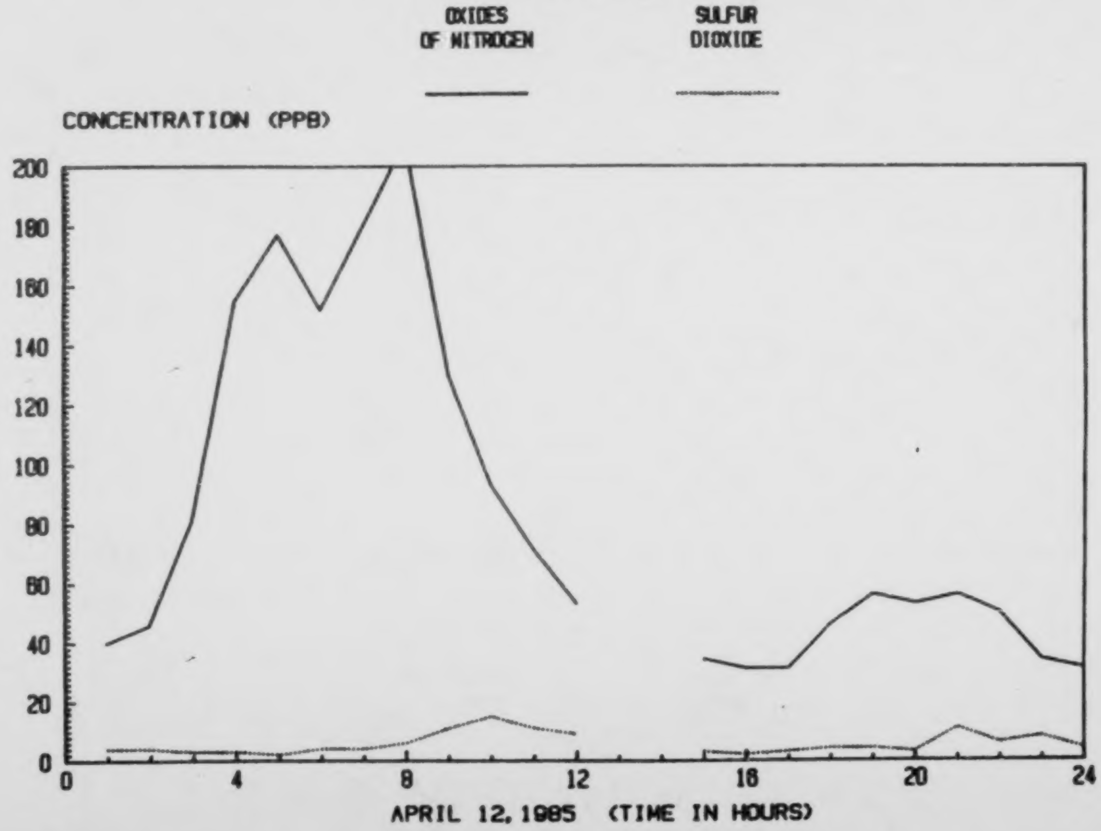
INDOOR POLLUTANT MEASUREMENTS

FIGURE 5.

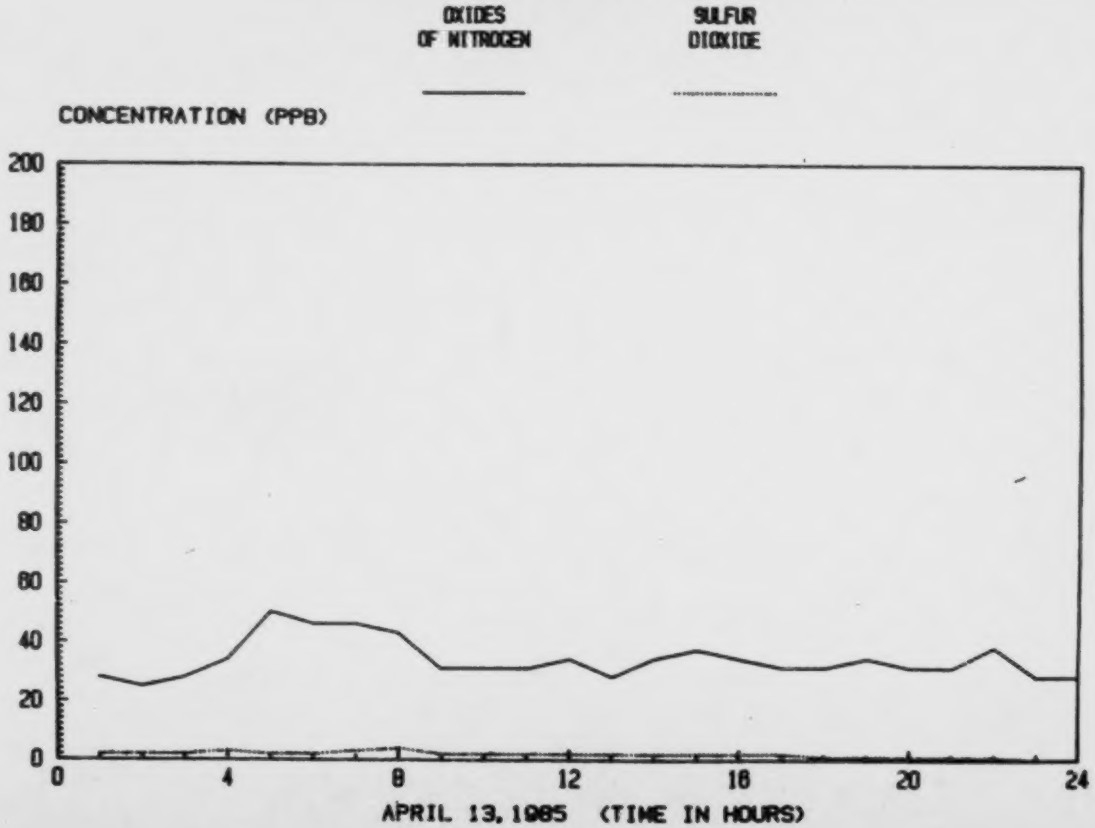


INDOOR POLLUTANT MEASUREMENTS

FIGURE 6.

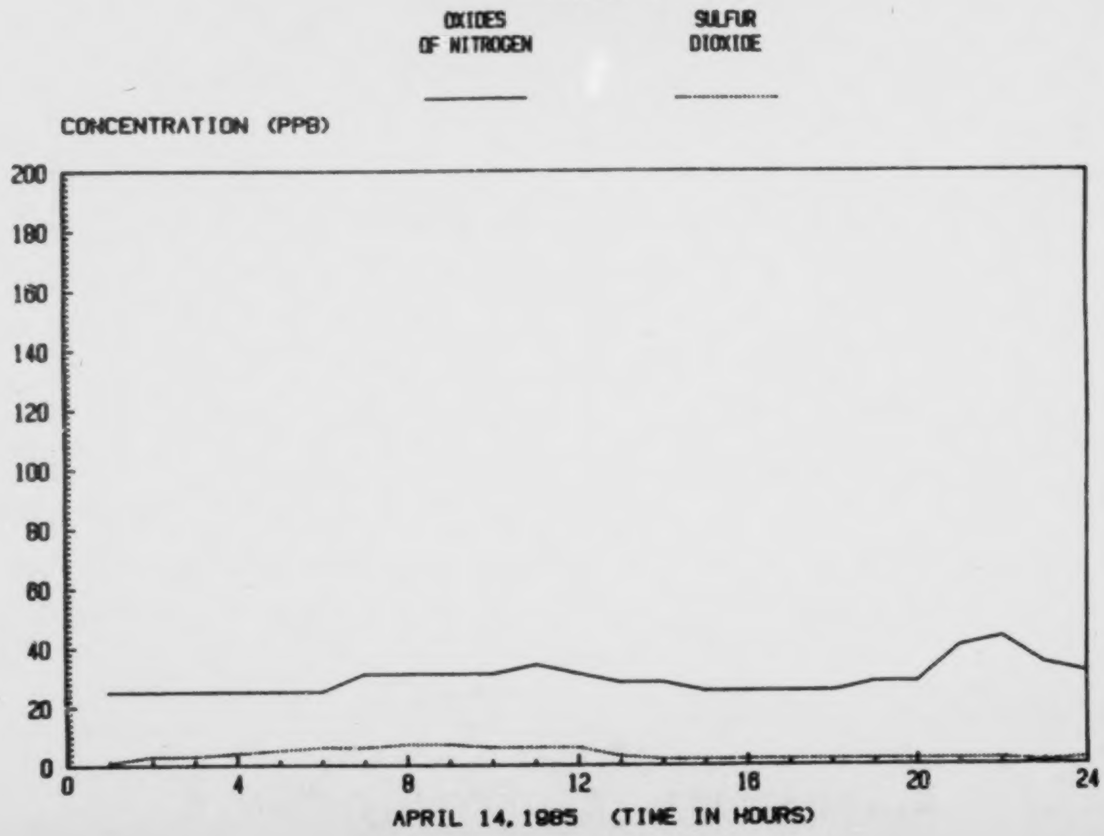


INDOOR POLLUTANT MEASUREMENTS
FIGURE 7.



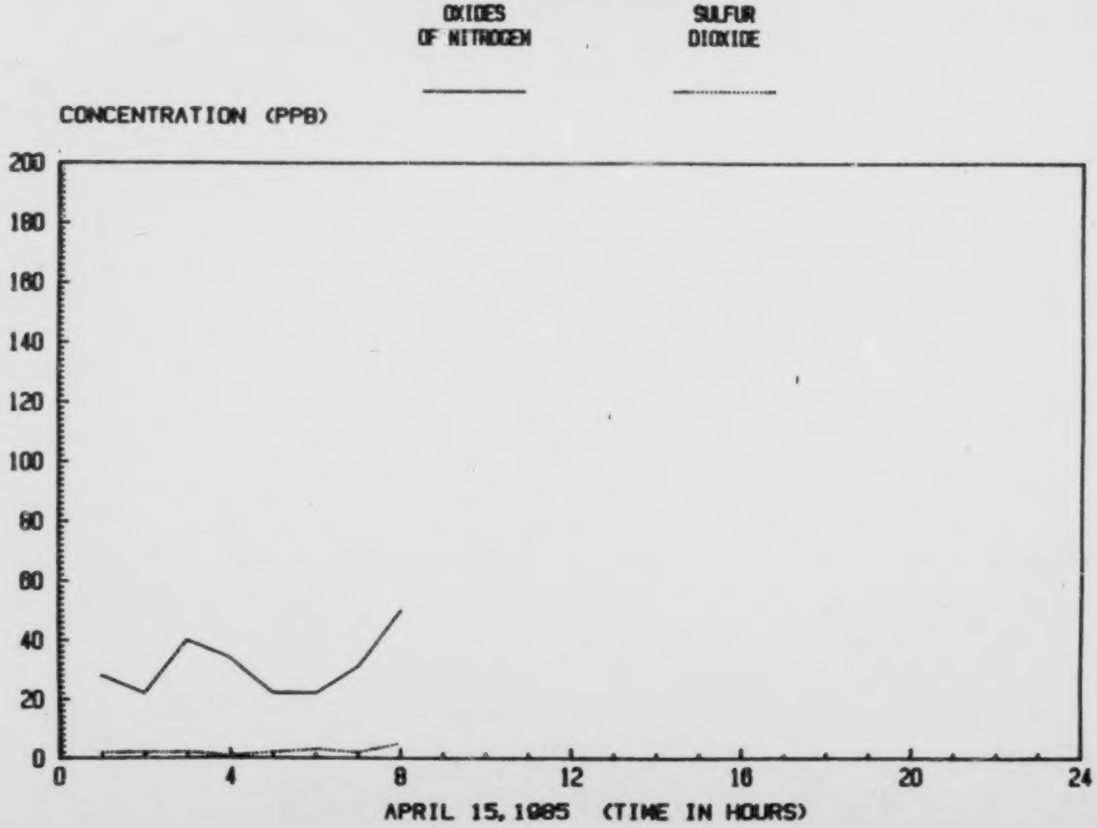
INDOOR POLLUTANT MEASUREMENTS

FIGURE 8.



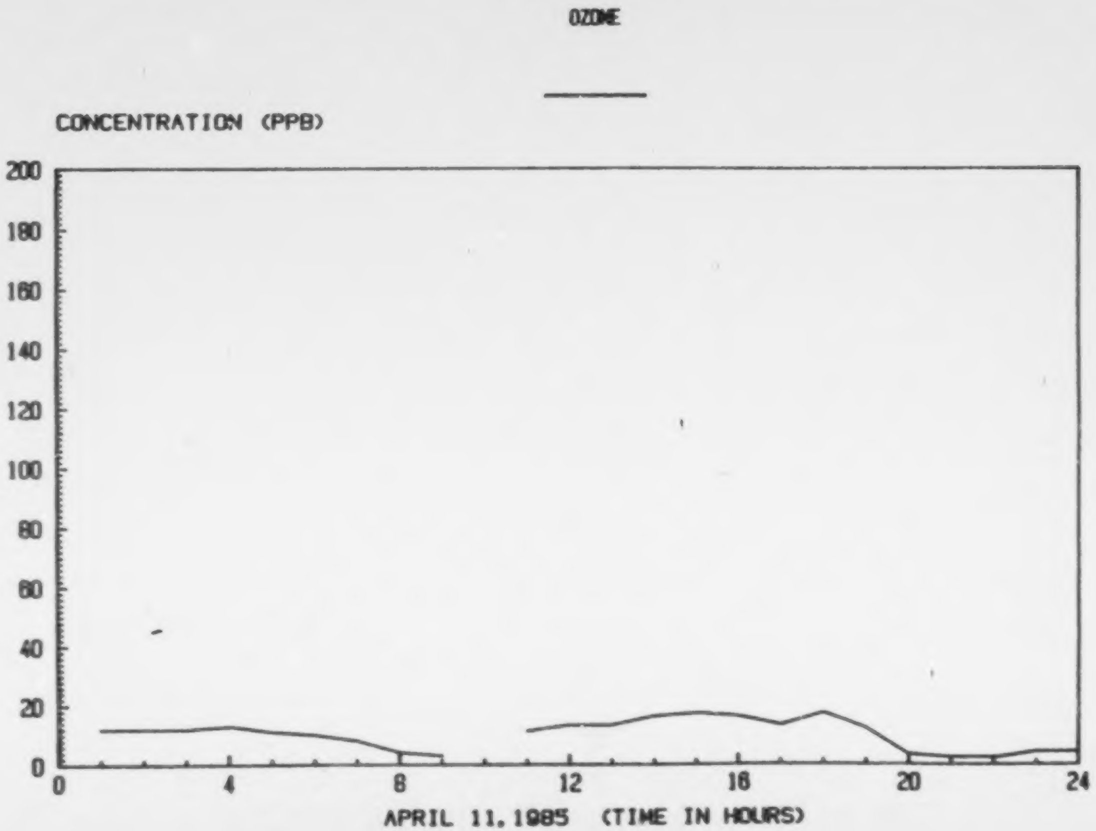
INDOOR POLLUTANT MEASUREMENTS

FIGURE 9.

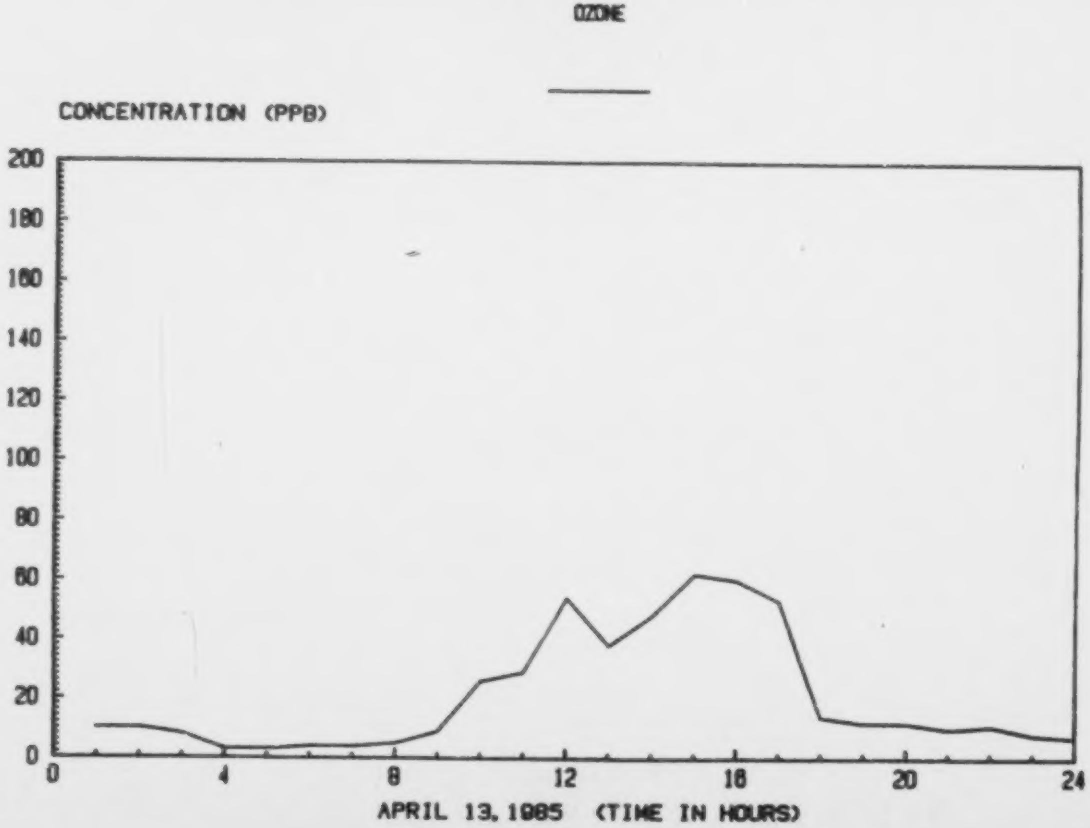


INDOOR POLLUTANT MEASUREMENTS

FIGURE 10.



INDOOR POLLUTANT MEASUREMENTS
FIGURE 11.



Appendix 5

DRAFT PRESERVATION POLICY

This Preservation Policy is established for the National Library of Medicine (NLM) pursuant to the authority contained in the National Library of Medicine Act of 1956 (P.L. 84-941), which charges the Library to "acquire and preserve ... library materials pertinent to medicine." NLM has an obligation not only to provide information needed by today's health professionals but also to ensure the availability of the scholarly biomedical record for future generations.

NLM's preservation program is governed by the guidelines for selection of the biomedical literature for the NLM collection, as described in the Collection Development Manual of the National Library of Medicine. NLM's principal responsibility is to ensure the preservation of the core biomedical literature that it collects at the comprehensive level. The Library has a lesser responsibility to assist in the preservation of literature in the subjects related to medicine and health that it collects at the research level. NLM assumes no responsibility for preservation of materials in subjects it collects at the basic information level. Within these parameters NLM must ensure that the biomedical literature is preserved. The preservation of NLM's own collection is a major step toward the preservation of the entire scholarly biomedical record. NLM also has a responsibility to assist the preservation of important biomedical literature held by other U.S. institutions. NLM's preservation efforts should be coordinated with those of other national libraries, research libraries and biomedical libraries.

Subject to the coverage guidelines in the Collection Development Manual, NLM seeks to preserve biomedical literature in all formats, including printed works, manuscripts, prints, photographs, audiovisual programs, and any additional formats that the Library may acquire in the future.

Although most items in the NLM collection may be retained in the original form as long as they remain useful, NLM's primary preservation responsibility is for the content of the biomedical literature rather than its original format. The need to preserve the original format as well as the content of the literature varies depending on the nature of the literature. In general, the items in the NLM collection with high intrinsic value are rare books, manuscripts, prints, and photographs, but individual items that deserve preservation in the original format may be found throughout the collection.

Preservation of all the core biomedical literature that NLM collects at the comprehensive level is desirable and probably achievable. In assigning preservation priority to groups of material, consideration shall be given to:

- uniqueness of the material
- level of use of the material

- state of deterioration of the material
- existence of preserved originals or preservation copies at other institutions
- relationship of the material to existing cooperative preservation activities
- availability of suitable preservation methods

The NLM staff shall monitor developments in preservation techniques to ensure the use of the most cost-effective methods available and shall participate in research, development, testing, and evaluation of preservation technology. In selecting specific techniques for particular groups of material, the staff shall consider the likely future demand for the material, ease of use of the preserved originals or preservation copies, the cost and reliability of the preservation method, the cost of long-term storage of the preserved originals or preservation copies, and other factors as appropriate.

Operational guidelines and procedures for selecting items to be preserved, choosing preservation techniques, and processing items for preservation shall be detailed in a manual to be developed and amended from time to time in a manner to be determined by the Director.

Definitions:

- "Biomedical" shall mean pertaining to health care, to the practice of the science and art of medicine broadly conceived, or to those branches of life sciences which are fundamental to that science and art.
- "Literature" shall be construed to include information not only in the form of the written or printed word, microforms and graphic materials, etc., but also such non-print information formats as audiotapes, videotapes, films (both still and motion picture), slides, computer tapes, etc.
- "Preservation" is the management of library materials to ensure their availability for use by future generations. Preservation encompasses such diverse activities as maintaining an appropriate storage environment, minimizing use practices that are harmful, providing physical or chemical protection to items, and making copies of literature in archival formats.
- "Comprehensive Level" shall describe a collection in which a library endeavors, so far as is reasonably possible, to include all significant works of recorded knowledge (publications, manuscripts, other forms) in all applicable languages, for a necessarily defined and limited field.

This level of collecting intensity is one that maintains a "special collection;" the aim, if not the achievement, is exhaustiveness. Older material is retained for historical research.

NLM collects the core biomedical subjects at the comprehensive level.

- "Research Level" shall describe a collection that includes the major published source materials required for dissertations and independent research, including materials containing research reporting new findings, scientific experimental results, and other information useful to researchers. It is intended to include all important reference works and a wide selection of specialized monographs, as well as a very extensive collection of journals and major indexing and abstracting services in the field. Older material is retained for historical research.

NLM collects these subjects it defines as related to medicine at the Research Level. Selections in these subjects are generally in English and selected foreign languages only. The selected foreign languages are usually French, German, Japanese, and Russian, but may vary depending on the primary centers of research in particular subject. Special language criteria, if any, are described under the individual subject.

- "Basic Information Level" shall describe a collection of up-to-date general materials that serve to introduce and define a subject and to indicate the varieties of information available elsewhere. It may include dictionaries, encyclopedias, selected editions, surveys, bibliographies, handbooks, a few major periodicals, in the minimum number that will serve the purpose. A basic information collection is not sufficiently intensive to support any courses or independent study in the subject area involved.

NLM collects those subjects it defines as peripheral to medicine at the Basic Information Level. Selections in these subjects are generally in the English language only.

Appendix 6

Proposed Preservation Section: Rationale and Functions

The formation of a new Preservation Section in the Reference Services Division is considered the most suitable option for a new organizational unit for the following reasons.

1. Policy, planning, and most operational responsibilities are combined in one place so there is less potential for coordination problems and no split between the "glamorous" and "routine" aspects of the job.

2. Most preservation workers are together under a single line authority.

3. The size of LO senior staff and number of people reporting to ADLO remain unchanged.

4. The responsibilities of the Office of the Chief, RSD, remain the same.

5. The healthy tension between service demands and preservation considerations remains within RSD.

6. A new Section with responsibilities comparable to existing LO Sections can be formed within the existing LO staffing level.

Other options, including a small Preservation Office reporting directly to the Office of the Associate Director for Library Operations and a Preservation Division, appear to have significant disadvantages with NLM's current organizational context. (A discussion of the various organizational options considered by the Planning Team appears in the "Report of the Task Force on Organizational Responsibility for Preservation Activities.")

The new Preservation Section should be assigned the following responsibilities (asterisks denote functions not currently performed by any NLM unit):

Management

* 1. Coordinate the development of preservation policies (including preservation priorities, copyright implications, and use of archival copies).

* 2. Plan and coordinate preservation programs.

3. Identify budget and staffing needed.

4. Initiate and manage contract actions. (HMD will share this function.)

* 5. Evaluate effectiveness of preservation programs.

Cooperative Programs

* 6. Work with publishers to promote original publication on archival quality materials, reprinting of important works, etc.

* 7. Consult with professional societies when determining preservation priorities.

* 8. Develop cooperative preservation activities with other national libraries, research libraries (ARL, RLG, etc.), U.S. biomedical libraries (the RML network), and foreign national libraries.

* 9. Share preservation information, including what has been preserved.

Collection Maintenance

10. Bind library materials.

11. Make minor repairs.

Technical Preservation/Conservation

* 13. Monitor developments in preservation techniques, equipment, supplies and programs.

* 14. Evaluate preservation impact of equipment and supplies used in processing and service activities.

15. Monitor and control environmental conditions.

16. Select items to be preserved. (HMD will share this function.)

17. Search to determine if preservation copies already exist.

18. Preserve library materials by appropriate

methods. (HMD will share this function.)

Education/Public Information/Consultation

19. Train staff in the safe handling and processing of material.

20. Provide users with information/training on how to use material without causing unnecessary damage.

21. Provide consultation/education to other biomedical libraries, special collections in medical history, etc., regarding preservation issues and methods.

Research

22. Identify appropriate research efforts to be undertaken in conjunction with the Lister Hill Center and/or other organizations.

The following preservation functions should continue to be handled by other units:

1. Collection maintenance - storing and controlling the collections, gapping, shelfreading. (Circulation and Control Section, RSD)

2. Collection integrity and security - preventing and detecting theft, guard force orientation and liaison, disaster prevention (including fire, water damage, mutilation, vandalism, etc.). (Circulation and Control Section, RSD; HMD; OA)

3. Preservation and collection maintenance activities related to special collections (e.g., manuscripts, prints and photographs, rare books). (HMD)

4. Research related to preservation. (Lister Hill Center)

In developing the plan for implementing the new Section, care should be taken to clarify its relationship to the other units that will continue to exercise responsibility for some preservation-related activities. Tables 7 and 8 provide a summary of recommended preservation activities and budget levels for the next five years.

A. INTRODUCTION

In 1983, Library Operations (LO) senior staff developed a strategic plan for 1984-88 which includes as one of its four broad objectives:

> to develop and implement a program for the preservation of the biomedical literature.

Preservation of the scholarly records is one of the most important challenges facing research libraries today, requiring significant expenditures of resources, the interest and involvement of all staff who process or use the collection, active cooperation among many institutions, and new organizational approaches.

As a first step toward developing NLM's preservation program, the Associate Director for Library Operations appointed a senior Preservation Planning Team on August 29, 1984. The members of this group are:

Duane Arenales
Acting Chief, Technical Services Division, LO

James Cain
Acting Chief, Reference Services Division, LO

John Parascandola, Ph.D.
Chief, History of Medicine Division, LO

Mark Rotariu
Chief, Office of Financial Management, Office of Administration

Linda Watson
Head, Audiovisual Resources Section, RSD, LO

Betsy Humphreys - Chairperson
Deputy Associate Director, LO

George Thoma, Ph.D. - Consultant
Chief, Communications Engineering Branch
Lister Hill Center

The Team has been asked to:

1. Assess the current physical state of the collection.
2. Assess the conditions under which the collection is used, processed, and stored.
3. Examine current preservation activities in all LO components.
4. Identify and evaluate available preservation techniques.
5. Identify current and potential cooperative preservation activities.
6. Develop a plan for the preservation of the NLM collection which includes recommendations for:
    - a. organizational responsibility for NLM preservation activities
    - b. general guidelines for selecting items to be preserved and assigning preservation priorities
    - c. methods for preservation of various parts of the collection including cost data and selected schedules
    - d. necessary changes to environmental conditions and processing and use practices
    - e. cooperative activities NLM should participate in or initiate

The report of the Preservation Planning Team is due in May 1985.

The planning process being used for this project is modeled on a self-study procedure developed by the Office of Management Studies (OMS) of the Association for Research Libraries (ARL) and described in Preservation Planning Program: An Assisted Self-Study Manual for Libraries. NLM has contracted with OMS for assistance in developing the plan and the results of NLM's effort will be shared with the ARL and biomedical library communities. Ms. Jutta Reed-Scott serves as principal OMS consultant to NLM for the project.

The planning process consists of three phases. During the first phase, the Preservation Planning Team reviews basic preservation issues; assembles background information about the library to provide a context for the examination of its preservation needs; and defines the next phases of the planning process, including their schedule, objectives, and participants.

The second phase involves a variety of Task Forces gathering and analyzing data and developing recommendations in several specific areas affecting preservation, e.g., the environment in which the collection is housed, the present physical condition of the collection, organizational responsibility for preservation activities.

In the third and final phase, the Preservation Planning Team studies the information assembled by the Task Forces, weighs alternative approaches, and develops a recommended plan of action.

This document is the outcome of the first phase of the planning process. It is organized into the following Sections:

A. Introduction
B. Institutional Setting of the National Library of Medicine
C. Preservation History and Practices
D. External Factors Affecting NLM's Preservation Program
E. Planning Methodology

B. INSTITUTIONAL SETTING OF THE NATIONAL LIBRARY OF MEDICINE

HISTORY

The National Library of Medicine can trace its origin back to 1818 or 1819 when the Surgeon General of the United States Army, Joseph Lovell, began to acquire books and journals needed for his work. However, the year of birth of the Library is generally considered to be 1836, when a request for funds for books ($150.00) first appeared in the estimate of expenses for the Surgeon General's Office. Under the direction of John Shaw Billings from 1865 to 1895, the collection of books began to take shape as a library, where in one place were assembled and organized the major medical books, journals and other important medical documents of Western Civilization.

In 1922, the Library of the Army Surgeon General's Office became the Army Medical Library, and three decades later, a joint agency of the three military departments. In 1956, Senators Lister Hill and John Kennedy submitted to Congress Bill S. 3430, "to promote the progress of medicine and to advance the national health and welfare by creating a National Library of Medicine." The bill was passed by Congress and signed into law on August 3, placing the Library within the Public Health Service. Funds were authorized for the construction of a new library building on the grounds of the National Institutes of Health in Bethesda, Maryland. Occupancy began in 1962, although the Library did not formally become a Bureau of NIH until 1968, the administrative structure which exists today. From a few books in a physician's office, NLM has become the world's largest research library in a single scientific and professional field, serving as a national resource for all US health professionals.

MISSION

The Act establishing NLM as a national library in 1956 (PL-84-941) authorized NLM to perform the following functions:

1) acquire and preserve library materials pertinent to medicine;
2) organize the materials by appropriate cataloging and indexing;
3) provide information about the materials in the collection through publication and other means;
4) make materials in the Library's collection available through loans, photocopies or other methods;
5) provide reference and research assistance; and
6) engage in such other activities as deemed appropriate.

LIBRARY RESOURCES AND ORGANIZATION

The National Library of Medicine is divided into 5 major divisions: Library Operations, the Office of Computer and Communications Systems, Specialized Information Services, the Lister Hill National Center for Biomedical Communications and Extramural Programs. Overall policy direction and administrative services are carried out by the Office of the Director and the Office of Administration. The current full-time permanent staff of NLM is 487. With part-time and other personnel, the total FTE equivalent is 536.

NLM's FY 1985 budget is $55,910,000. Over the past five years, there has been a trend of moderate growth. Excluding additional funds realized in FY 1985 for extramural grant programs, the total NLM budget has grown at an average rate of about 4% per year. It is reasonable to assume continued overall growth at the same rate for at least the near future. The budget for literature acquisition has increased at a greater rate to keep pace with inflation and this is also likely to continue.

Library Operations (LO), the largest of NLM's five Divisions, performs the first five of the Library's mandated functions and assists in the performance of the sixth. Its FY 1985 budget of $17,081,000 includes salaries, literature acquistions and other support costs such as equipment and contract activities. The current full-time permanent LO staff of 234 (350 total FTEs) is divided into four divisions: Technical Services (TSD), Bibliographic Services (BSD), History of Medicine (HMD), Reference Services (RSD), and two other units, Medical Subject Headings (MeSH) Section and the Regional Medical Library (RML) Program.

The Lister Hill National Center for Biomedical Communications is the division of NLM responsible for research and development activities. Currently the Center is investigating the potential of optical disc technology for document preservation, storage and retrieval which may eventually be applied to the Library's preservation problem. Approximately $650,000 in FY 1985 funds are devoted to this project.

The Library collects materials comprehensively in all major areas of the health sciences and to a lesser degree in such areas as chemistry, physics, botany and zoology. The collections today stand at 3.1 million items in a variety of formats including books, journals, audiovisual materials, microfilm, manuscripts and prints and photographs. An annual literature budget of about $2.2 million supports the acquisition of approximately 16,000 books and 1,000 audiovisuals, 23,000 serial titles, 33,000 manuscript items, and 450 prints and photographs.

The Library's computer-based Medical Literature Analysis and Retrieval System (MEDLARS) was established to achieve rapid bibliographic access to NLM's vast store of biomedical information. MEDLARS is used to generate a number of catalogs and indexes, and its machine readable databases are available for online searching directly on the NLM computer and through commercial database vendors and international cooperative partners that lease NLM files. Last year some 2.5 million computerized searches of these databases were performed on the NLM system alone. The availability of information about NLM's collections through this mechanism increases the demand for physical access to the materials themselves. Lending and other services are coordinated through a Regional Medical Library Network with the NLM as the "library of last resort" for the location of hard to find or unique items. Some 2 million interlibrary loan requests are filled each year within this network; NLM accounts for over 142,000 of these. The Library circulated an additional 211,000 volumes to onsite patrons in the Reading Room in FY 1984.

PRESERVATION IMPLICATIONS

The Act establishing the Library gave NLM responsibility for preservation of the literature pertinent to medicine. Although significant attention has been devoted to preservation activities at NLM already, NLM's printed collections contain the seeds of their own destruction in the form of high acid content paper which, over time, causes discoloration, embrittlement, and finally disintegration. In addition, the Library faces special problems related to the conservation and preservation of the archival microfilm and historical motion picture film collections and the History of Medicine Division's manuscripts, older printed works, prints and photographs.

If NLM is to carry out its statutory mandate successfully, the Library must develop a more comprehensive approach to preservation that makes effective use of existing resources, emerging technologies, and cooperative arrangements with other libraries. To this end, LO has identified the development and implementation of a preservation program for the biomedical literature as one of its four broad objectives for FY 1984-88.

C. PRESERVATION HISTORY AND PRACTICES

THE COLLECTIONS

The small collection of books and journals in the Surgeon General's Office initially grew rather slowly. The Library's first catalog, a handwritten manuscript prepared in 1840, records only 134 titles, representing some 200 volumes. It was far smaller at the time than many personal libraries of physicians, not to mention the libraries of various medical societies and institutions. When the Library came under the charge of John Shaw Billings in the fall of 1865, it still contained only about 1,800 volumes. Under his direction the collections expanded dramatically. Sometime during 1871, a decision was made to broaden the objectives of the Library to include service to the entire American medical profession, not just the military. By the time Billings left the Library in 1895, the collections had grown to encompass some 73,475 books, 39,412 volumes of journals and transactions, and over 200,000 individual pamphlets and theses. During Billings' tenure, the Library also made its first significant efforts to acquire rare books, manuscripts, and prints and photographs in the history of medicine.

Over the course of the twentieth century the collections continued to grow as the National Library of Medicine became the largest institution of its kind in the world. The collections of printed materials now total some 500,000 monographs, 700,000 bound serial volumes, 170,000 pamphlets and 280,000 dissertations. In addition, the small special collections, such as manuscripts and photographs, have expanded into large collections directed by specialized librarians. The Library currently houses about 70,000 prints and photographs and over 1,000,000 manuscript items.

The variety of formats collected also increased. The incorporation of the National Medical Audiovisual Center into the Library in 1967, for example, led to a program of active acquisition of audiovisual materials. Today the audiovisual collection consists of some 6,000 videocassettes, 9,000 audiocassettes, 2,000 16mm films, 2,000 historical films, 1,000 filmstrips and 240,000 slides. The Library's microform holdings total approximately 34,000 reels of microfilm and 122,000 microfiche. Technology continues to add to the types of formats which the Library collects (e.g., computer software, videodiscs).

The formats represented in the Library's collections are as follows:

1. Printed Literature (books, journals, pamphlets, etc.)
2. Manuscripts
3. Art Prints
4. Photographs
5. Oil Paintings (a small number, but a few are valuable)
6. Microfilm and Microfiche
7. Videotapes
8. Audiotapes
9. Slides and Filmstrips
10. Motion Picture Films
11. Pre-Columbian Art (about 40 clay sculptures)
12. Computer Tapes and Discs
13. Videodiscs

There may be a small number of other types of materials (e.g., phonograph records) contained in the collections, but the above categories would appear to include all of the formats that are relevant to the present preservation study.

Because of its archival responsibility, the Library has not had a systematic policy for weeding the collections (except in the case of added copies). By and large items incorporated into the collections are retained, although materials considered out of scope or peripheral are periodically withdrawn upon the recommendation of staff members. There is no written policy concerning replacement of lost materials, but current works which are still in print are ordinarily replaced if identified as lost. The Library also actively seeks to fill gaps in its journal runs.

PHYSICAL FACILITIES

In the early decades the small collection of publications moved with the Surgeon General to various offices. From 1862 to 1866, the Surgeon General's Library was housed in the front parlor of a two-story building which had originally been a private home. It was adjacent to and owned by the Riggs Bank located at Pennsylvania Avenue and Fifteenth Street, N.W. In 1866, the Library moved to a remodeled Ford's Theatre, which was closed and purchased by the government after the assassination of President Lincoln. The collections remained in Ford's Theatre until a new building was constructed on the mall specifically to house the Surgeon General's Museum and Library. The new quarters were occupied in August of 1887, and this structure continued to house the Library until the present building in Bethesda was ready for occupancy in 1962.

Physical conditions for the storage of rapidly expanding collections were poor in the post-Civil War years. Ford's Theatre had been hastily erected and was poorly constructed. The increasing weight of books, museum specimens, etc. placed stresses on the floors and walls that the building had not been designed to bear. (In fact, the interior collapsed during renovations in 1893, a few years after the Library had moved out of it.) The building was also not fireproof.

The building on the mall provided the Library with a decent, if not ideal, home for the first time. The structure, with its brick walls, concrete floors, and ironwork, was practically fireproof. Billings himself designed the 25-foot-high iron book stacks. The Library had no artificial illumination (except for a few gas lights) until it was wired for electricity in 1900. The building was heated by hot air from a coal-fired steam boiler, and a few fireplaces, but Library Hall was so large that it proved impossible to warm adequately on extremely cold days. Needless to say, temperature and humidity must have fluctuated widely during the course of the year.

Certain rare books (e.g., incunabula) had been segregated from the collection and housed in display cases even when the Library was still in Ford's Theatre. Many of the Library's historically valuable books and manuscripts, however, were scattered throughout the stacks with other publications. It was not until the Second World War that a separate History of Medicine Division was established and the historical collections brought together in one place. Fear that Washington might be bombed led to a concern on the part of libraries and museums for the protection of the nation's cultural treasures. A decision was made at the Army Medical Library to find a home in the midwest for the Library's pre-19th century books, and the Allen Memorial Library Building of the Cleveland Medical Library Association was selected. Beginning in August of 1942, 952 boxes of historical materials were sent to Cleveland. Although the books were originally scheduled to return after the war, because of lack of space in the building on the mall the historical collections remained in Cleveland until the new building in Bethesda was occupied in 1962.

During the war space became an increasing problem for the Library. Tens of thousands of books had to be housed in other buildings in the mall area. Some of these buildings were temporary structures and provided poor physical conditions for the books. The main Library building itself was suffering from deterioration due to age and lack of proper maintenance and leaked badly during heavy rain.

The completion of a new building on the NIH grounds provided the Library with greatly improved physical facilities. The Bethesda building is constructed of reinforced concrete and steel with exterior walls of limestone, granite and marble trim. Much of the structure, including most of the shelving for books, is below ground level, reflecting the concern of civil defense planners of the 1950's for potential atomic attack. This defensive planning also led to the insertion of narrow, recessed windows on the main floor.

The building is heated by low pressure steam and air conditioned. Preliminary data suggest that temperature control may be a lesser problem than humidity control. Temperature seems to be in the 70° range year round. There is some humidity control but available evidence suggests that humidity may range from as low as 35% in the winter to 55% or above in the summer. Fluorescent bulbs in the stack areas are supposed to be covered with ultraviolet filter sleeves, but this is not always the case. Sleeves may not always be replaced when bulbs are changed. It is also not clear whether the fluorescent bulbs in some areas with glass-paneled ceilings, such as the prints and photographs room in the History of Medicine Division (HMD), have filter sleeves. According to the building engineer, air entering the Library is filtered only for dust. There is no chemical filtration to eliminate acid fumes such as sulfur dioxide.

The building is protected against fire by a water sprinkler system. The rare book collections (incunabula room and B1 stacks in HMD) are protected by a carbon dioxide fire extinguisher system. The Library has in the past considered replacing carbon dioxide with halon, which presents less of a threat to the safety of employees, but no action has been taken in this direction. In accordance with the federal policy of "self-insured" protection, neither NLM nor its collections carry special insurance against damage or loss.

Facilities for exhibiting portions of the collections, which is done on a regular basis and frequently involves rare books, are not ideal. The cases used have locks, but would be easy to open. The plastic tops do not filter out ultraviolet radiation from natural or artificial light.

The Library's security system includes electronic surveillance and a search of bags, briefcases, etc. by a guard as patrons and staff leave building 38. Large portions of the collection, including rare books and manuscripts, are not provided with security labels and would therefore be undetected by the electronic security system. Access to the historical collections is more restricted, however, than access to the general collections. There is no evidence that loss by theft has been great over the years, but the theft of an infrequently used item can go undetected for a long time.

The Library is fortunate in not having suffered any major disasters. A disaster plan was implemented in 1979 and revised in 1983. The emphasis of the plan is on water damage.

COLLECTION MAINTENANCE PRACTICES

The collections are largely housed in metal stacks. Journals from the period 1871-1969 are housed in compact shelving and it is anticipated that over the next two years many more items will be transferred to existing or newly-installed compact shelving (e.g., 1970-1974 journals, nineteenth century books and journals, HMD pamphlets and dissertations). It would be worth investigating whether long-term storage in compact shelving creates unique preservation problems. For example, could it lead to high concentrations of certain pollutants in a localized area?

Certain specialized collections are housed under special conditions. Archival microfilm and the historical film collections are preserved in special cold storage vaults. Acid-free Hollinger boxes and folders are used to house the collections of personal or organizational papers in the Modern Manuscripts collection in HMD. Fine art prints are stored flat in special cases.

In one sense, access to the Library's collections is limited in that the stacks are closed to the public. Except for NLM staff, readers may not check out materials but must use them in the Reading Room. There are exceptions to the closed stack policy, however, and stack passes to the general collections are not infrequently given to readers who can demonstrate a need to use a large body of literature, such as long runs of journals. The History of Medicine Division does not issue stack passes.

In another sense, however, access to the collections is much more open because of the interlibrary loan process. The great majority of interlibrary loan requests are for current journal articles, and these are handled by sending out photocopies, but monographs and videocasettes from the general collection are regularly sent out on interlibrary loan to requesters in the United States and Puerto Rico unless they are in poor condition. Journals and all audiovisual formats may also be loaned to the NIH Library. The History of Medicine Division also sends out some original items on loan (e.g., current books on medical history housed on its reference shelves). Most items in the historical collections are not loaned in the original, but are microfilmed or photocopied.

Materials coming into the Library receive a good deal of handling in processing. Items are checked in, catalcged, stamped, marked, labelled with security labels and machine-readable identifiers (MRIs), shelved, and in some cases indexed. The impact of these procedures on preservation has not been fully examined. For example, does the adhesive used to affix labels contain acids or other chemicals which might damage the books or audiovisuals?

Journals are bound with a class A binding (standard library binding). Softbound books have traditionally been bound in the same way. Acid-free end papers are used. There has been relatively little in the way of repair of bindings of items in the general collections. Some items have been rebound when necessary. In recent years, questions have been raised about the advisability of rebinding certain items, or about binding all softcover books in the first place. Each time a book is bound or rebound, there is a loss in trim, which can lead to tightly bound volumes which are difficult to use or copy. The repair and rebinding of rare books is discussed below.

Library materials also are subject to wear and tear through reader use. Items can also be damaged in shipment on interlibrary loans. Photocopying of books and journals can be hard on the materials, especially if done carelessly. Possibly more attention should be devoted to training staff and patrons in how to handle materials when photocopying. Perhaps greater restrictions should be placed on photocopying of certain materials by patrons. It would also be worthwhile to investigate whether the present photocopy machines in the library could be replaced by machines which cause less damage to materials. Microfilming causes less damage to books than photocopying, but nevertheless involves some wear and tear on the materials. The same is true for the photographic processes used to prepare photographic prints, slides or negatives from visual materials in books or in the prints and photographs collection.

Patrons are not permitted to do their own photocopying of rare books, manuscripts or prints and photographs. The History of Medicine Division ordinarily microfilms materials from rare books, but may use a photocopy machine instead if only a few pages are involved. Modern manuscripts are often photocopied for patrons. Sometimes original photographs are photocopied, a procedure which may not be advisable unless some type of protective filter device is available to reduce exposure of the photograph to harmful radiation.

EVOLUTION OF NLM PRESERVATION ACTIVITIES

The term preservation is used in this report in a broad sense. To quote from the ARL Preservation Planning Program self-study manual which has guided the work of this Preservation Planning Team:

> The preservation of a library's collections and/or of the information contained within its collections is dependent on a broad spectrum of environmental conditions, processing and storage procedures, binding and repair practices, use patterns, replacement policies, and a complex set of technical problems related to the physical components of the materials themselves.

Many activities that go on in the Library could therefore be considered as relating to preservation. This section will focus, however, on significant efforts undertaken by the Library for the specific purpose of preserving some portion of the collection.

Perhaps the first large-scale preservation effort undertaken by the Library took place while the historical collections were in Cleveland. When the books arrived in Cleveland, it was found that several thousands of them were in poor condition. Covers were warped, spines were broken, pages were loose, leather bindings were torn and crumbling, etc. It was estimated that three-foureths of the pre-1800 volumes needed restoration. In 1943 a contract was entered into with the National Library Binding Company, East Cleveland to repair and rebind the early books and to machine-bind later books, pamphlets and documents. Over the next twelve years, 10,317 operations were carried out on 9,917 volumes. Original bindings were repaired if practical, but a decision was made to treat the books as part of a research library and not as museum pieces. Therefore many books were rebound to restore them to a coudition where they could be handled easily and without damage.

No further preservation work was done on the historical collections after their move to Bethesda until 1969. In that year the Library began contracting with experienced hand book binders to restore or rebind rare books. Between 1969 and 1982 a total of 3,407 volumes were restored or rebound. At the present time the Library is budgeting $37,000 per year for the treatment of rare books (oiling of bindings, deacidification, repair, restoration, and rebinding).

Another current preservation activity in the History of Medicine Division is a project involving the transfer of the Library's collection of portraits to acid-free folders and boxes. Two valuable oil paintings, the portraits of Billings and of Fletcher, are also being cleaned and restored.

One of the major preservation concerns facing libraries today involves post-1850 printed works. Mass produced chemically digested woodpulp paper entered commerce around 1850 and most books and journals published since 1870 were printed on it. This paper is inherently weak because of the short fibers in wood pulp and because of its relatively high acid content. Consequently many of NLM's post-1850 books and journals are steadily deteriorating, the pages becoming brittle and crumbling. Beginning in the 1950's the Library initiated a program of microfilming the badly deteriorated materials. A survey indicated that the shelves of the Library held about 350 million pages, over 90% of which had been printed since 1870 on woodpulp paper. Some 37 million pages were considered to be fully deteriorated, and it was estimated that number would increase to 262 million by 1989. In 1966, the Library increased the pace of the microfilming program under contract with commercial firms and also made several large scale purchases of commercially microfilmed serials. Although the Library continues to slowly build an archival microfilm collection through the microfilming of items requested on interlibrary loan which are considered too valuable or too fragile to send in the original, the large-scale preservation microfilming program came to an end in 1982 largely because of the promise of new technologies and the difficulties in selecting which small percentage of the total should be filmed with the limited resources available. About 2,000 serial titles and 3,000-4,000 monographs from the period 1871-1906 were microfilmed during the course of the program.

Experiments conducted at the Library's Lister Hill Center and at the Library of Congress have been exploring the potential of optical disc technology for mass storage of text. Various institutions, including the Library, have also been investigating the potential of videodisc for the storage of graphic images. The Lister Hill Center and the History of Medicine Division have completed an experimental videodisc containing about 1,000 images from the prints and photographs collection. Although this technology may not eliminate the need to store the original image, it has preservation implications as the handling of original materials will be greatly reduced if patrons and staff can use the disc for searching the collection to locate desired images. Similarly, the Library's historical film collection is being transferred to video tape so that the tapes may be viewed instead of the original films. Some $70,000 has been budgeted for the activity in FY 1985, which will accommodate approximately 10% of the present historical film collection.

D. EXTERNAL FACTORS AFFECTING NLM's PRESERVATION PROGRAM

NLM's preservation program must take into account a number of external factors affecting the U. S. information and biomedical communities. These include publishing trends, developments in the concept of intellectual property, changes in the ways health professionals acquire and use information, the emergence of preservation as a critical concern, and an increased emphasis on cooperative library activities.

PUBLISHING TRENDS

Publishers are the primary source of NLM's raw materials--the books, periodicals, audiovisuals, prints and other library materials which make up the Library's collection. The publishing industry, therefore, initially determines the dimensions of the preservation problem which NLM will face.

For over a 100 years the trend has been toward lower cost, higher speed production of an ever increasing flood of publications, which because of the acid paper, adhesives and binding techniques used in their manufacture, are subject to rapid deterioration. As the library community has become more aware of the inherent weakness of the materials it collects, it has attempted to pressure publishers to shift to methods which will ensure more durable products. Partially as a result, this fall the National Information Standards Organization (NISO) will publish a standard for permanent durable paper with alkaline reserves. However, on the whole, the U.S. publishing industry appears to see little or no economic advantage in producing more durable print products.

The definition of a "publication" has changed with the emergence of new media. An increasing amount of material is published in microform, especially computer-output-microfiche (COM); however, this medium too is subject to gradual destruction. Audiovisuals and electronically-based forms of information are proliferating daily and will present the Library not only with bibliographic, acquisition and service problems, but also with difficult preservation problems.

INTELLECTUAL PROPERTY

Related to publishing trends are a spectrum of issues concerned with intellectual property rights. The question of who shall be reimbursed for what kinds of use of what kinds of "publications" is under continuing review as information becomes an increasingly valuable commodity. This in turn affects the form and conditions under which publications may be reproduced or re-stored for preservation purposes. State of the art videodisc and optical disk technology for mass storage also may lend themselves to ready redissemination of information. As a result efforts to provide technical solutions to mass preservation problems may become enmeshed in the issues of intellectual property rights.

NLM's public information activities and their effect on the private sector have been subject to close scrutiny for the past several years, and this is an issue to which we must be particularly sensitive.

CHANGES IN THE WAY HEALTH PROFESSIONALS ACQUIRE AND USE INFORMATION

Health professionals traditionally have demanded rapid access to information. Health sciences librarians traditionally have responded by providing the best or developing the newest in information services. In the last ten years microcomputer technology and the proliferation of online databases have profoundly affected the way health professionals acquire and use information. Artificial intelligence systems, electronic publishing, and developing "electronic colleges" have the potential for making even more significant changes. If current trends in hospital economics continue, there will be few libraries available close at hand to fill immediate needs. It is likely that there will be increasing numbers of technologically sophisticated physicians tapping into remote information resources both for current and older materials. The challenge to NLM then is not just to preserve the biomedical literature, but to preserve and store it in ways which will facilitate access for our user community and be appropriate to their changing needs.

EMERGENCE OF PRESERVATION AS A CRITICAL CONCERN

Over the last 25 years the Council of Library Resources (CLR) has acted as a catalyst to focus the attention of the library community on preservation as a critical concern. In large measure as a result of CLR's efforts, significant progress has occurred in three areas. The first is a developing consensus on the dimension of the preservation problem which libraries collectively face, a recognition of the cost of confronting it and of the cost of failing to confront it. The second is a developing research effort which addresses methods to prevent or retard deterioration of library materials on the one hand and methods for mass storage of already deteriorated materials or as a prospective preservation measure on the other. A number of efforts have concentrated on the development of an effective, affordable deacidification, or as it might more accurately be termed a neutralization process, for the acid paper already present in millions of volumes.

The Library of Congress has patented a mass deacidification process using diethyl zinc (DEZ) vapor and recently received funding for a facility capable of processing 500,000 volumes per year. LC plans to treat its annual intake of about 300,000 monographs plus 200,000 older volumes. A cooperative plan for preserving medical works in this way could perhaps be negotiated with LC. There are two other deacidification systems, the Wei T'o being tested by the Public Archives of Canada and an unnamed process developed by the Koppers Company of Pittsburgh. The University of California at Berkeley has announced plans to undertake independent testing of the three techniques with results expected to be available sometime in 1985.

Both NLM and the Library of Congress are actively engaged in research to test the application of videodisc and optical disc technology for preservation purposes. LC is testing a commercial analog videodisc system to store a variety of graphic materials including motion pictures and prints and is developing an optical digital disc system to test storage of about half million pages a year of material from high use serials. Plans are now in place to test user response to the systems at LC.

NLM's Lister Hill National Center for Biomedical Communications has demonstrated the feasibility of video disc technology for storage of medical prints and photographs and also has completed the first phase of a research and development program in electronic document storage and retrieval.

Preservation has emerged as a specialty within the library profession. Interest and expertise has spread beyond the circle of archivists and rare book librarians. Beginning in 1981,Columbia University announced a degree program for conservation and preservation and the number of courses, workshops, and institutes announced by other library schools and organizations has proliferated. While there is a developing pool of trained and partially trained preservationists, there also is a developing demand for this type of expertise. The October issue of American Libraries, for example, listed several positions available in the field of preservation.

The Association of Research Libraries Office of Management Studies has developed a Preservation Planning Program "to enable academic libraries to identify and address preservation problems". The National Endowment for the Humanities has awarded the Association a two-year grant to fund ten ARL institutions to serve as demonstration sites for the program during 1984-1986. Participation in the program is expected to result in a report and action plan for each institution to enhance its preservation goals and to provide a thorough test of the OMS program as a blueprint for other libraries. NLM, though not a recipient of NEH grant funds, has selected the ARL/OMS program to structure its planning effort.

COOPERATIVE LIBRARY ACTIVITIES

In 1959 reports of studies by William J. Barrow, a Virginia document restorer, on the physical strength and stabilization of modern book papers began to alert the library community to the present state of and future dangers to their collections. In 1960 after a discussion of Barrow's findings, the Association of Research Libraries appointed a standing committee on Preservation of Research Library Materials. According to Pamela Darling, noted preservation specialist with ARL, this led over the next 12 years to the "articulation of a broad-scale cooperative approach to the nation's preservation problems." In 1962 CLR, which had partially funded Barrow's research, funded an ARL study to provide a framework for national planning by assessing the "magnitude of the paper-deterioration problem." The study concluded that in terms of pages rather than titles, 60 percent of the material listed in the National Union Catalog in 1961 was probably printed on paper subject to rapid deterioration. A second CLR funded effort was mounted to find a solution to the paper-deterioration. The result, a study by Gordon Williams entitled The Preservation of Deteriorating Books: An Examination of the Problem with Recommendations for a Solution concluded that the best way to deal with the problem was to establish a federal agency which would preserve a physical copy of each significant work and make copies available to other libraries. ARL adopted the report and in 1965 called for the Library of Congress to take on this responsibility. In 1965 the Librarian of Congress accepted the challenge and stated that the "Library of Congress will assume responsibility for a national program for the preservation of deteriorating books in accordance with the principles set forth in the Report. . . by Gordon R. Williams."

Through ARL the CLR provided funding for the Pilot Preservation Project at the Library of Congress to begin this work and LC initiated research which led to the about to be implemented mass storage and deacidification projects.

In 1976 LC called for a "Planning Conference for a National Preservation Program". The Conference identified research, educational and cognitive efforts as critical to resolving the problem of deteriorating library materials. An ad hoc advisory committee to LC was established and met twice focusing its attention "on the need for automated bibliographic control of microforms as the foundation for a coordinated preservation filming program." In the late 1970s LC went through a series of reorganizations and budget reductions. According to Darling, this resulted in a concentration on its own preservation problems and at least a temporary turning away from a national program.

The same time period saw the beginning of a number of other cooperative efforts. The American Institute for Conservation began to place increased emphasis on library materials, and in 1973 a National Conservation Advisory council was established "to serve as a forum for cooperation and planning" related to the conservation of cultural property. The Harvard, Yale, Columbia, New York Public Library consortium, which later served as the nucleus for the Research Libraries Group (RLG), established an active preservation committee, and initiated RLG's cooperative efforts to bring together bibliographic data for members' master negative microfilms. With funding from the National Endowment from the Humanities RLG members input into the RLIN database records for more than 25,000 microfilm masters held by member libraries. LC has announced plans to participate in this effort. The project is primarily intended to prevent duplication of filming efforts. More immediately it has resulted in the publication in June 1984 of the first edition of the RLG Preservation Union List. The RLG Medical and Health Science Libraries Program Committee at its October, 1984 meeting indicated that member institutions plan to develop a cooperative approach to preservation of their biomedical collections.

In 1981 ALA established a division level Committee on the Preservation of Library Materials and in 1982 the OCLC Research Library Advisory Committee established a task force charged with studying the feasibility of tagging online records to identify volumes that have been designated as preservation copies. ARL has continued its strong interest in preservation, developing the self-assisted process for preservation planning that NLM has adopted and emphasizing the development of preservation programs in its member libraries in the ARL strategic plan. CLR currently is planning major new initiatives in the areas of preservation and LC has announced an international preservation meeting to be held in Washington in the summer of 1985.

Within the medical library community, the Union Catalog of Medical Periodicals in the Greater Northeastern Region represents an early effort to identify cooperative responsibility for retention of medical periodicals and the Pacific Southwest Region has developed a cooperative retention plan for serial titles. The current three year Regional Medical Library (RML) Program (1983-85) funded by NLM called for cooperative collection development activities, but not for preservation per se. Planning for the next three to five year period places increased emphasis on preservation.

The Library Operations (LO) five year plan calls for developing cooperative preservation activities among health science libraries, among libraries with collections in the history of medicine and among the three national libraries. Ongoing discussions with the Library of Congress and the National Agricultural Library intended to reduce duplication of effort by more clearly defining the three institution's areas of responsibility for acquisition and bibliographic control of material should be broadened to include other service responsibilities including preservation. Cooperative efforts are essential as federal deficits and pressures to decrease expenditures in the non-defense sector are likely to result in increased competition among government agencies for available dollars. Within NLM the preservation program will face tough competition from other high priority programs.

In 1984 the arena of cooperative preservation activities is large and diverse. There is no monolithic national plan, but a sometimes confusing diversity. The task before NLM is to become better acquainted with existing and planned cooperative efforts and to provide the leaderhip necessary for an effective national program for preservation of the biomedical literature.

E. PLANNING METHODOLOGY

BASIC ASSUMPTIONS

The Act creating the National Library of Medicine gave the Library responsibility for the preservation of the biomedical literature. Drawing on the responses to a Delphi instrument on scope and coverage issues recently completed by many NLM staff, the RML Directors and Associate Directors, and a few contact people identified by the MLA/NLM Liaison Committee, the Preservation Planning Team has developed the following interpretation of NLM's Preservation mission:

1. NLM has responsibility to ensure that substantive biomedical literature is preserved, but need not do all the preservation work itself. Its preservation efforts should be coordinated with those of other national libraries, research libraries and biomedical libraries.

2. NLM has preservation responsibility for literature in all formats (e.g., printed, audiovisual, machine readable) and its preservation plan should reflect this. As described

previously, the following types of materials are represented in the NLM collection now and should be addressed in the Plan:

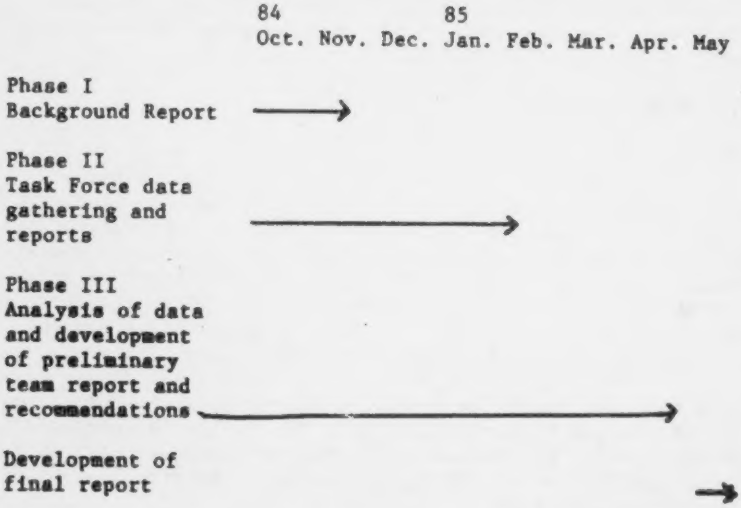
- Printed literature
- Manuscripts
- Pictures
- Microforms
- Videotapes and Audiotapes
- Slides and Filmstrips
- Motion Picture Films
- Computer tapes and discs
- Videodiscs

3. NLM's primary preservation responsibility is for the content of the biomedical literature rather than its original format. The need to preserve the original format as well as the content of the literature varies depending on the nature of the literature. In some cases it may be necessary to destroy the original format in order to preserve the content in a cost-effective and usable manner.

This view of NLM's preservation responsibility will govern the development of the plan.

SCHEDULE

The timetable for development of the Preservation Plan is as follows:



The distribution of this background report marks the conclusion of Phase I.

TASK FORCE CHARGES AND MEMBERS

During the next phase of the preservation planning process, separate task forces will gather information and develop recommendations in the following six areas:

1. Physical condition of the collection.
2. Conditions under which the collection is stored, processed, and used.
3. Organizational responsibility for preservation activities.
4. Available preservation techniques/methods.
5. Cooperative preservation activities appropriate for NLM.
6. Disaster recovery planning.

Each Task Force will contain staff from a variety of LO and NLM components; most of the Task Forces will be headed by a member of the Preservation Planning Team.

Although each Task Force has its own specific charge, the general purpose of all six groups is to provide the Preservation Planning Team with background information and suggested courses of action which can be reviewed and considered in developing the NLM Preservation Plan. All Task Forces are expected to use applicable standards and guidelines and to build on any relevant data collection activities undertaken at NLM in the past.

Each Task Force will begin work on November 26, 1984, and will submit its report to the Team by February 15, 1985. During this same period, the Team will develop draft guidelines for selecting items to be preserved and assigning preservation priorities. In early February, there will be a combined meeting of all the Task Forces in which each will present a summary of its findings and recommendations. After this meeting, the Team will analyze all the reports and begin work on the overall Preservation Plan. The tentative deadline for completion of the Plan is May 30, 1985.

1. Physical Condition of the Collection

The purpose of this Task Force is to:

1. Determine methods for assessing the condition of a variety of types of material in the NLM collection. This includes identification of:
    - sampling techniques
    - elements of the material to be examined
    - criteria for determining degree of deterioration
2. Assess the condition of each type of material.
3. Produce an inventory of the general state of each type of material.
4. Identify specific problem areas (i.e., materials in deteriorated condition) by category, e.g., date range, country of origin.
5. Rank problems, based on the physical condition of the materials.

Chair: Jim Cain, RSD, LO

Members: John Horne, RSD, LO
Alice Ladson, RSD, LO
Alex Nobleman, RSD, LO
Young Rhee, HMD, LO
Carol Spencer, LO
Carol Unger, RSD, LO

2. Environmental Conditions for the Collection

The purpose of this Task Force is to:

1. Produce an inventory of current environmental conditions in which the collections are stored or displayed. This activity includes:
   - ° determination of the specific conditions (e.g., temperature, humidity, light, air quality, physical structures for storing the material) to be evaluated
   - ° identification of the various locations to be monitored
   - ° collection and summarization of environmental data
2. Compare NLM's environmental conditions and use practices with generally accepted standards and the practices of other institutions with effective preservation programs.
3. Identify any specific problems with NLM's environmental conditions, including any which contribute to the possibility of disaster or are likely to hamper responses to disaster.
4. Identify methods for correcting any problems, including consideration of off site storage, and give the pros and cons and costs of each.
5. Recommend actions to be taken to correct or avoid the problems.

Chair: Mark Rotariu, OFM, OA

Members: Doralee Agayoff, RSD, LO
Herbert Crigger, NIH
Jay McNeave, RSD, LO
Karen Patrias, RSD, LO
Patricia Ruben, OAMS, OA
Norman Smith, LO

3. Processing and Use Practices

The purpose of this Task Force is to:

1. Describe current processing and use (including security considerations) of the collection as they affect the condition of the material. This activity includes:

   - identification of types of use, use policies and their effects on the collection.

   - identification of types of processing (e.g., labeling, shelving, binding, filming, mailing, reproduction) and processing policies and their effects on the collection.

   - identification of equipment used for processing, viewing, or reproducing materials and their effects on the collection.

2. Compare NLM's use and processing practices with generally accepted standards and the practices of other institutions with effective preservation programs.

3. Identify any specific problems with NLM's use and processing activities, including any which contribute to the possibility of disaster or are likely to hamper responses to disaster.

4. Identify methods for correcting any problems and give the pros and cons and costs of each.

5. Recommend actions to be taken to correct or avoid problems.

Chair: Linda Watson, RSD, LO

Members: Kevin Beverly, RSD, LO
Rosellen Muniak, TSD, LO
Eileen Murtagh, TSD, LO
Nancy Selinger, BSD, LO
Manfred Waserman, HMD, LO

4. Preservation Techniques/Methods

The purpose of this Task Force is to:

1. Inventory and compare available preservation techniques and methods for the various types of material in the collection, with emphasis on deacidification, mass disc storage, microfilm, film preservation, and acquisition of materials in archival formats. Information gathered on each method should include:

   ° material for which it is suitable

   / ° pros and cons of its use including:
   effect on public service and staff activities,
   longevity
   potential adverse effects on users, staff,
   or material
   resistance to disaster
   historical experience with technique
   industry support for technology

   ° cost - initial and ongoing

   ° impact on implementation schedule

2. Evaluate the most promising methods as to their suitability for use at NLM, either for retrospective or prospective collections.

3. Make recommendations on methods which should be used or evaluated further by NLM.

Chair: John Parascandola, HMD, LO

Members: George Cosmides, SIS
Peter Krivatsy, HMD, LO
Dianne McCutcheon, TSD, LO
Sarah Richards, RSD, LO
George Thoma, LHC
Philip Teigen, HMD, LO

5. Organizational Responsibility for Preservation Activities

The purpose of this Task Force is to:

1. Develop an inventory of current NLM preservation activities which includes:
    - ° organizational component(s) involved
    - ° number and kind of FTEs involved
    - ° current budget for the activity
2. Examine the organization of preservation activities in other organizations with effective preservation programs.
3. Identify any problems with the organization of preservation activities at NLM.
4. Recommend any changes to the organization of preservation activities at NLM, including summarizing the qualifications for and duties of any new positions needed.

Chair: Betsy Humphreys, LO

Members: James Cassedy, HMD, LO
Judith Duff, LO
Lillian Kozuma, LO
Jacque-Lynne Schulman, RSD, LO
Sheldon Kotzin, BSD, LO, Consultant

6. Cooperative Preservation Activities

The purpose of this Task Force is to:

1. Identify existing cooperative activities which could assist NLM in fulfilling its preservation mission, including any in which NLM already participates.
2. Identify any new cooperative activities needed to fulfill this mission.
3. Assess the advantages and disadvantages, and probable cost of each.
4. Make recommendations for NLM leadership of and/or participation in cooperative activities.

Chair: Duane Arenales, TSD, LO

Members: Jeanne Brand, EP
Martha Fishel, TSD, LO
Becky Lyon-Hartmann, RML, LO
Scott Plutchak, BSD, LO

7. Disaster Recovery Task Force

The purpose of this Task Force is to:

1. Review and evaluate NLM's current Disaster Recovery Plan to ensure that it:
   - covers adequately all types of materials in the NLM collection
   - deals with the effects of the various kinds of disasters which are most likely to befall the NLM collection
   - compares favorably with good examples of Disaster Recovery Plans prepared by other institutions
2. Make any necessary changes to the Disaster Recovery Plan.

Chair: Carol Ditzler, RSD, LO

Members: Norman Smith, LO
Ione Auston, RSD, LO

Appendix 2

List of Task Force Members

1. Physical Condition of the Collection

Chair: Jim Cain, RSD, LO

Members: John Horne, RSD, LO
Alice Ladson, RSD, LO
Alex Nobleman, RSD, LO
Young Rhee, HMD, LO
Carol Spencer, LO
Carol Unger, RSD, LO

2. Environmental Conditions for the Collection

Chair: Mark Rotariu, OFM, OA

Members: Doralee Agayoff, RSD, LO
Herbert Crigger, NIH
Jay McNeave, RSD, LO
Karen Patrias, RSD, LO
Patricia Ruben, OAMS, OA
Norman Smith, LO

3. Processing and Use Practices

Chair: Linda Watson, RSD, LO

Members: Kevin Beverly, RSD, LO
Rosellen Muniak, TSD, LO
Eileen Murtagh, TSD, LO
Nancy Selinger, BSD, LO
Manfred Waserman, HMD, LO

4. Preservation Techniques/Methods

Chair: John Parascandola, HMD, LO

Members: George Cosmides, SIS
Peter Krivatsy, HMD, LO
Dianne McCutcheon, TSD, LO
Sarah Richards, RSD, LO
George Thoma, LHC
Philip Teigen, HMD, LO

5. Organizational Responsibility for Preservation Activities

Chair: Betsy Humphreys

Members: James Cassedy, HMD, LO
Judith Duff, LO
Lillian Kozuma, LO
Jacque-Lynne Schulman, RSD, LO
Sheldon Kotzin, BSD, LO

6. Cooperative Preservation Activities

Chair: Duane Arenales, TSD, LO

Members: Jeanne Brand, EP
Martha Fishel, TSD, LO
Becky Lyon-Hartmann, RML, LO
Scott Plutchak, BSD, LO

7. Disaster Recovery Task Force

Chair: Carol Ditzler, RSD, LO

Members: Norman Smith, LO
Ione Auston, RSD, LO

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

Division of Research Resources

REPORT ON PLAN TO ADDRESS THE IMMEDIATE AND LONG RANGE FINANCIAL NEEDS OF THE REGIONAL PRIMATE RESEARCH CENTERS

Thomas E. Malone

Thomas E. Malone, Ph.D.
Deputy Director, NIH

January 1986

REPORT ON PLAN TO ADDRESS THE IMMEDIATE AND LONG RANGE FINANCIAL NEEDS OF THE REGIONAL PRIMATE RESEARCH CENTERS

INTRODUCTION

In its report on the Fiscal Year 1986 budget for the Department of Health and Human Services, the House Committee on Appropriations stated:

> "The Committee is becoming increasingly concerned over the level of funding for the primate centers located throughout the country. It is imperative that these centers maintain the highest standards in the care and treatment of animals. As a result, the Committee requests the Division of Research Resources (DRR) Director to prepare a plan to address the immediate and long range financial needs of these centers. The plan should be made available to the Committee before its consideration of the 1987 budget." (House Report No. 99-289, page 76)

The following report has been prepared by the National Institutes of Health of the Department of Health and Human Services in response to this request.

BACKGROUND

The National Institutes of Health (NIH) recognized the value to biomedical and health research of establishing a durable network of primate research centers, regional and national in scope, almost three decades ago. Responding to an NIH proposal to establish seven regional primate research centers, Congress appropriated funds in 1960 and 1961 to purchase land, construct buildings, and provide for the ongoing operational support of the centers. By 1965 construction of facilities was complete and the seven centers located in Beaverton, Oregon; Covington, Louisiana; Atlanta, Georgia; Seattle, Washington; Madison, Wisconsin; Southboro, Massachusetts; and Davis, California, were operating. These same centers presently make up the Regional Primate Research Centers Program (RPRC). The mission of the RPRC Program is to provide specialized resources (physical facilities, technology, professional and technical staffing, and a variety of primate species) for research studies applicable to the solution of human health problems.

This program involves the cooperation of major academic institutions and allows the pursuit of many types of biomedical studies that require the use of nonhuman primates. The numerous contributions made by the centers during the past 20 years in the areas of reproductive biology, population control, maternal-infant relationships, disease of the newborn, mental retardation, nutrition, infectious diseases, cardiovascular diseases, diseases of the central nervous system, and behavioral sciences leave little doubt of their importance to the health and well-being of mankind. In addition to investigations of human health-related problems, the centers study naturally-occurring diseases of primates, methods for primate husbandry and care, and breeding techniques to increase the supply of primates.

The facilities and resources of the centers are available to affiliated and collaborative investigators, visiting scientists, graduate students, and postdoctoral students. The centers are also national resources for biological materials (e.g., blood, sera, tissue) and information derived from nonhuman primates that are needed by scientists working elsewhere.

CENTER ADMINISTRATION AND OPERATION

The Division of Research Resources (DRR) supports the seven centers with base operating grants. These peer-reviewed resource grants provide a stable, long-term source of support for administrative, service, and core research costs, including salaries of members of center core staff. Each center has a director and a core staff of professional and supporting personnel.

NIH base operating grants generally provide no more than half of a center's annual budget. Research grants and contracts awarded by Public Health Service (PHS) agencies to core scientists and collaborating or affiliate investigators also provide support, as does funding from other federal agencies and sponsors. Cooperative projects are also sponsored in centers by commercial and industrial organizations such as drug and pharmaceutical firms. Center host and grantee institutions have, in many cases, provided significant support on a cooperative or matching basis. A good example of such a cooperative effort is the building recently purchased by a host institution that will be renovated with special federal improvement funds to provide facilities that are needed for accreditation of the center's animal care program.

IMMEDIATE CENTER NEEDS

An extensive assessment of center needs was undertaken in 1983 as a result of increasing recognition that center physical facilities and equipment, with an aggregate value of more than $100 million, were seriously deteriorating and becoming out of date. An evaluation panel of outside experts noted the fact that the centers had been constructed in the early 1960s and that repairs, remodeling, and in some cases, expansion of physical facilities were necessary. Similar concerns were expressed about worn out and obsolete equipment, particularly inadequate caging and housing for center animals. These problems made it unlikely that each center could continue to provide optimal care and maintain accreditation by the American Association for the Accreditation of Laboratory Animal Care (AAALAC). They also seriously threatened the center program goal of becoming self-sufficient in breeding the most commonly used species. The results of this assessment showed that accomplishing needed center improvements would cost $13.5 million.

A five year program was begun in 1984 to address these needs with an earmark of $1.0 million included in report language in the 1984 appropriation bill. Additional Federal allocations totalling $2.5 million through FY 1984 and 1985 have made possible a number of improvements. These have included the replacement of leaking roofs, upgrading sewage systems, bringing utility services up to code, providing sources of emergency power, purchasing modern caging, and renovating and re-equipping animal facilities and laboratories. The substantial progress made has resulted in six of the seven centers now being accredited by AAALAC, and the expectation that the seventh one will be accredited within the next year. Unforeseen expenses have been added this year to the improvement program. The basic reference document for implementation of the Public Health Service's animal welfare policy, the "Guide for the Care and Use of Laboratory Animals" as revised in 1985, now recommends larger cages for one of the most numerous classes of macaque monkeys. Purchase of these cages and provision of the space that will be necessary to accommodate them will cost approximately $2.0 million. With the incorporation of this change, it is estimated that a total of $12.0 million will be required for completion of the program in addition to the $3.5 million that has already been allocated.

LONG TERM NEEDS OF THE PRIMATE CENTERS

Principal long term center objectives include assuring that: 1) programs of exemplary animal care are maintained, 2) there is improved accommodation to the needs of outside investigators, 3) continuing progress is made towards becoming self sufficient in producing those species needed in center programs that can be bred domestically, and 4) cooperative programs with institutions in source countries are strengthened to provide access to those species that cannot be bred in sufficient numbers domestically.

Experience has shown that center facilities and programs must be more responsive to changing circumstances and research needs if they are to fulfill their intended purpose. For example, the appearance of diseases such as acquired immunodeficiency disease (SAIDS) now makes it clear that present facilities in many cases must be improved to provide an environment that better limits transmission of this disease. Similarly realization of the great potential SAIDS offers as a model for studies of human AIDS has been slowed because of limited laboratory and containment space. Demands on facilities are also occurring because of the increasing value and scarcity of primates. Monkeys are being kept longer, used less in terminal studies, and shared more often; accordingly they are becoming older and larger. For example, the proportion of larger monkeys in the colony of one center has doubled in just four years. The scarcity of nonhuman primates and the resource intensive and long term nature of research associated with their use is also resulting in requests by an increasing number of outside investigators to use the centers. In many cases, these investigators cannot be supported because available space and other center resources are already fully committed.

Overall, the most pressing long term need is for space for additional animal holding and for breeding. Specifically, additional facilities of appropriate design are needed for 1) studies that require isolation, such as the development and testing of candidate vaccines against human AIDS, and 2) better separation and protection of valuable breeding colonies that cannot be replaced. An associated requirement is for additional space and equipment for laboratory services and studies, particularly in the areas of microbiology and immunology. Such space would provide not only better support for the work of outside investigators, but also for more extensive center colony health surveillance and pilot studies like those that led to the identification and characterization of the AIDS model.

The cost of meeting these currently identified long term needs is estimated at a total of $5 million for equipment purchases and alteration or renovation of physical facilities and $5 million for construction during the next five year period above and beyond the current modernization and improvement program. However, these requirements cannot be reasonably addressed in the absence of construction authority for the centers program.

More extensive involvement by the Primate Centers is needed in establishing conservation and resource management programs in those countries that still must be relied upon for supply of certain species of nonhuman primates needed in biomedical research and testing programs. Good examples are the South American owl monkey needed in vision and infectious disease research and the Indonesian Celebes black ape for research on diabetes. Recent severe losses in Celebes black apes from simian acquired immunodeficiency disease have left insufficient animals in the United States to assure successful breeding. Potential opportunities do exist in both South America and the South Asia regions that would help to assure the future availability of these and other species. It is estimated that an additional $1.0 million per year would be needed for at least five years to support technical cooperation and assistance in the areas named that could be helpful in assuring the supply of these and other species.

PLAN TO ADDRESS PRIMATE CENTER NEEDS

For meeting short term center needs, the highest priority for available funds is assigned to physical facility alterations and renovations and equipment purchases that have already been identified in the current five year improvement and modernization program. A primary objective is assuring that accredited center programs of animal care remain so and that the single center presently not accredited achieves and maintains that status on the most rapid timetable possible. Successful fulfillment of many of the needs in this program is possible with continued allocations of federal funds. This funding will continue to be supplemented by contributions from host institutions and other sources. To meet additional needs that may occur, such as the current new requirement to provide larger caging, the currently conceived improvement program may have to be extended beyond 1989.

For meeting longer term center needs, DRR anticipates that funding will continue on a level basis. Some tradeoffs may be required to provide the resources necessary to support expanded breeding and animal holding programs and the needs of outside scientists. Level funding will be sufficient to provide adequate core operational support and the continuing improvement program. Matching funding from host institutions or other sources would be required for any center construction project to be supported with federal funds.

DRR plans to continue to encourage the development of sources of center funding other than the base operating grant. The development of cost recovery systems offers a good example of how other sponsors, primarily the categorical institutes of NIH, will increasingly help to support the costs of center operations. The cultivation of mutually beneficial relationships between the centers and organizations in the industrial sector also will continue. These approaches will broaden the base of sponsorship for research using center resources and will allow greater flexibility for program funding to meet critical center needs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

National Institute of Neurological and Communicative
Disorders and Stroke

Report on Rehabilitation-Related Research

Thomas E. Malone

Thomas E. Malone, Ph.D.
Deputy Director, NIH

February 1986

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

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National Institute of Neurological and Communicative
Disorders and Stroke

Report on Rehabilitation-Related Research

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Report on Rehabilitation-Related Research

Executive Summary

In House Report No. 99-289, the Committee on Appropriations of the House requested that the National Institutes of Health (NIH) prepare and submit a report on rehabilitation-related research (page 38). The following is submitted in response to that request.

Most of the Institutes of the NIH have a significant investment in rehabilitation-related research. In the last fiscal year for which complete data are available (fiscal year 1984), there were 688 individual projects, supported by a total of $78,694,000, that encompass a range of subjects as broad and as varied as the diseases, conditions, and disorders to which they relate either directly or indirectly.

Cooperation with other federal agencies is achieved through the coordinating responsibilities of the National Institute of Handicapped Research, as legislated in Section 202(a) of the 1978 Amendments to Public Law 95-602 for that purpose: "to promote and coordinate research with respect to handicapped individuals and to more effectively carry out the research programs under section 204 of the amendments." The mechanism promulgated within that legislation to implement the coordinating responsibilities of the National Institute of Handicapped Research is the Interagency Committee on Handicapped Research, with the Director of the National Institute of Handicapped Research serving as Chairman of that Committee.

The Director of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) is the representative of the Director, NIH, to the Interagency Committee on Handicapped Research and one of the representatives of 20 agencies that regularly attend the meetings of that Interagency Committee. Successful working relationships have been established with the National Council on the Handicapped and other groups and agencies that have an active interest in rehabilitation research. The NINCDS and the NIH will continue to participate in this effective means of coordinating and fostering federal programs of rehabilitation-related research and of sharing and promoting its own plans for the continuation of a substantial involvement in rehabilitation-related research.

Plans of the National Institutes of Health for research in areas related to rehabilitation call for attempts to maintain the research base to the extent that it is practical and realistic.

Report on Rehabilitation-Related Research

INTRODUCTION

In its report on the Fiscal Year 1986 budget for the Department of Health and Human Services, the Committee on Appropriations of the House stated:

> "The committee understands the need for a stronger commitment of the National Institutes of Health (NIH) to participate in rehabilitation research programs as they relate to the disabled. As a result, the Committee requests a report by the Director, broken down by institute, of rehabilitation related research programs. The report should also address issues of joint cooperation with other Federal agencies and what the NIH will do to foster more research in this high priority area."

As an area of endeavor, rehabilitation represents the attempts of society to meet the needs and to develop the full potential of handicapped children, to reduce human dependency, to increase self-reliance, and to fully utilize the productive capabilities of all handicapped people. For the purposes of obtaining information for this report from the Institutes of the NIH, the NIH has retained the definition of rehabilitation-related research provided by the Interagency Committee on Handicapped Research of the National Institute of Handicapped Research in their annual requests to the NIH for the same information. Accordingly, research related to rehabilitation of handicapped individuals generally includes all studies directed toward acquiring new or improved, or the modification of existing, knowledge applicable to or affecting functional restoration, improvement, or stabilization of physical, emotional, social, academic, and (or) vocational performance and independence of the physically and (or) mentally disabled. The following is a summary of the scientific and medical content of the rehabilitation-related research programs of the individual Institutes of the NIH. The number and amount of projects for each Institute are shown in the attached table.

RESEARCH PROGRAMS BY INSTITUTE

National Institute on Aging. The Institute, which supports research on the aging process and on the diseases and other special problems and needs of the aged, has a major investment in rehabilitation-related research, particularly in relation to effective functioning during middle and later years. Specific areas of rehabilitation-related research currently supported include stress and coping; cognitive deficits in Alzheimer's disease and senile dementia; urinary tract infectious and incontinence in the elderly; osteoporosis; accident prevention, particularly falls and fall-related consequences such as hip fractures; tactile aids for the deaf and the deaf-blind; psychosocial factors in nutrition, exercise, Alzheimer's disease, and senile dementia; productivity, work, and retirement; and health care in institutions and the home.

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. The Institute conducts and supports research on a number of diseases that are characterized by chronicity and long-term disabling effects rather than mortality. Consequently, much of the research on these diseases is, by their characteristic chronicity and disabling effect, rehabilitation related. These diseases include arthritic diseases and related rheumatic and connective tissue disorders; diabetes and other inherited errors of metabolism, including cystic fibrosis; diseases of the gastrointestinal tract, including diseases of the liver and gallbladder; endocrine disorders; diseases of the blood and bone; and kidney and urological diseases. The Institute also conducts and supports related research in orthopedic surgery, dermatology, nutrition in health, and nutrition-related disorders, most of which involves some aspect of rehabilitation as related to reducing dependency, increasing self-reliance, and improving the quality of life. The specific projects identified as rehabilitation related include studies of how mechanical factors maintain the integrity of articular cartilage or facilitate its breakdown; development of exercise models and prescriptions that would help in determining how exercise aids in the prevention, and may be used in the treatment, of coronary heart disease and other disorders; development of strength training and limb mimicking devices for physical therapy; computer-assisted patient education in physical therapy, for patients and families of patients with rheumatoid arthritis; evaluation of the efficacy of arthroscopic surgery and alternatives for the treatment of osteoarthritis of the knee; clarification of the safest means of rehabilitation of the knee through surgical reconstruction; determination of the ideal mechanical environment for fracture healing; development of laboratory tests for detecting and predicting corrosion of orthopaedic implants; and the development of a patient-oriented portable stimulator for treatment of hip disorders.

National Cancer Institute. The Institute's rehabilitation research emphasizes comparative studies, interventions, and evaluable demonstration projects on effective techniques, procedures, and protocols applicable to physical, psychological, social, and vocational functioning. Research may be directed towards current and former cancer patients and their families, health professionals, or community-based participation. The goal of cancer rehabilitation research is to maximize the patient's potential to return to full function to the greatest extent possible. Current research activities are concerned with continuing care research on identifying and reducing obstacles for cancer patients, which includes practical problems with specific service implications related to situations that may confound or limit the ability of cancer patients and their families to cope with the treatment and consequences of cancer, such as difficulties in arranging transportation and limitations in ambulation and self-care. A recent workshop on the effects of surgery on swallowing, which has permitted a review of what is known about the integration of treatment and rehabilitation in head and neck cancer, represents a first step in securing measures of functional rehabilitation as treatment sequelae. Because cancer, its treatment, and its aftermath have profound effects on the quality-of-life of patients and their potential for rehabilitation, a pilot study has been initiated to explore the feasibility of measuring quality-of-life issues associated with the treatment and care of cancer patients in selected Community Clinical Oncology Programs. This study should help establish whether quality-of-life measurements can be collected in the community setting and what practical considerations need to be built into any larger-scale research projects. The Institute has also initiated studies of interventions to improve the quality of survival for recovered childhood cancer patients, for whom numerous deleterious physical and psychosocial consequences have been documented. In the absence of research on how to manage the needs of these survivors, this initiative will encourage research to develop, implement, and evaluate interventions to prevent, reverse, or remediate long-term consequences among survivors of pediatric cancer and their families. Other current research includes several studies on cancer pain, psychosexual dysfunction after breast-cancer surgery, amelioration of the stresses of radiation therapy, and depression. New activities are concerned with the transfer of already available information on advances in the management of chronic pain to appropriate health-care providers; the development of educational interventions for targeted health-care professionals, primarily physicians and nurses; the development of survey techniques to describe accurately the proportion of all cancer patients who experience pain; and improvement in the management of chemotherapy-associated complications such as nausea and vomiting. As part of its joint cooperation with other federal agencies, the Institute also participates in the U.S. Public Health Service Interagency Committee on Pain and Analgesia, including the subcommittees on research and on education and training. The Institute is also active in the American Cancer Society's planning and coordination of rehabilitation service needs, for which that organization has the prime interest.

National Institute of Child Health and Human Development. The Institute supports research programs aimed at treatment of retarded children and any handicapping conditions associated with their disorders. Rehabilitation-related research, which is both biological and behavioral, emphasizes four general topics: learning, cognition, and memory in mental retardation; family relationships; the mentally retarded in community and institutional settings; and communication and language. The research on learning, cognition, and memory focuses on understanding how retarded children can learn to generalize from one learning task to others, the transfer of laboratory methods for improving learning to the classroom and other settings, and processes for integrating information from the different senses. Research on family variables is of special interest in relation to the national movement to provide home and family care for mentally retarded children rather than institutionalization. These studies focus on family life and its influence on parenting skill and interactions between retarded children and siblings. With concern for the total ecology of retarded persons, the Institute sponsors research that investigates how the retarded adapt to community and institutional life; what supportive services are available for the retarded in communities; how socioeconomic factors affect the development, care, and life outcome of retarded persons; and, similarly, how the community adapts to the presence of retarded persons in its neighborhoods. In the area of communication and language, a major emphasis is the development of speech and language in retarded persons, particularly the development of new ways for retarded children to communicate and understand communications directed to them. Included here are studies of verbal, written, and sign communication skills and communication problems in school and family settings.

National Institute of Dental Research. The Institute has a major interest in congenital and acquired craniofacial anomalies, with rehabilitation-related research on the understanding, medical management, rehabilitation, and prevention of these disfigurements. The effects of facial and cranial abnormalities are profound for the patient, the family, and society. The malformations often entail immediate and long-term major expenses for surgical, medical, and support services. Moreover, because of the essential functions of the mouth and head in vision and hearing, eating, breathing, speaking, and other important functions, the complications of craniofacial defects can be severe. Through research conducted or sponsored by the Institute, investigators are devising techniques to correct or to minimize these physically, and often psychologically, debilitating conditions. Since our understanding of craniofacial defects such as cleft lip and palate has benefited from advances in clinical genetics and cell biology, the Institute is supporting studies to search for genetic markers for these disorders, to detect efforts in the early stages of tissue formation, and to identify specific teratogens in abnormal development. Investigators continue to build on major advances in surgery to repair these anomalies, with special emphasis on speech and hearing aspects that enhance the patient's ability to function in society. Much of the insight gained from the multidisciplinary research on the normal process of growth, maintenance, and repair of craniofacial tissues applies to understanding and treating acquired defects caused by trauma or disease. To determine the extent of these injuries, researchers are examining the incidence of permanent disfigurement or loss of function from accidents, the costs of treatment, and the psychosocial consequences of these injuries to the patients and their families, In other research, grantees are developing prostheses that are life-like in color, form, function, and touch for facial restorations. Results of studies of wound healing, problems related to food and airway management, and speech difficulties resulting from cancer or injury are also providing information and techniques that may enhance the quality of life, with the ultimate goal of improving these patients' outlook for successful social, educational, and vocational involvement.

National Eye Institute. To meet the need for studies aimed at helping those who already have irreversibly impaired vision, the Institute supports research aimed at enabling partially sighted and totally blind people to perform important tasks in school, at the workplace, or in leisure activities. Part of this research is directed at better characterization of the effect of specific diseases on vision, one goal of which is to help people with such problems make the most effective use of their remaining sight. The Institute also recognizes the need for, and supports some research in, the design, development, and evaluation of optical aids; video magnification or image enhancement systems; methods for training people with impaired central vision to use their peripheral vision more effectively; and techniques for improving performance of visual tasks by substituting partially or completely for lost vision.

National Institute of General Medical Sciences. The rehabilitation-related research sponsored by the Institute is in two areas: the controlled release of macromolecules by surgically implanted drug-delivering devices and the digital control of rehabilitation-exercise machines. The former has been a field of increasing interest during the past decade, primarily because of its potential for decreasing dependence on cumbersome and immobilizing means of delivering medication during treatment and rehabilitation, but relatively little attention has been focused on the development of such systems for large-macromolecular-weight drugs such as polypeptides. Several years ago, investigators supported by the Institute were able to develop the first such biocompatible polymeric systems for delivering these large-molecular-weight drugs. On the basis of earlier observations, investigators are now addressing additional areas that should be significant in the future of controlled release systems for large or small molecules. In related research on an insulin-delivery device, the principal objective is to develop implantable bioerodible drug-delivery devices that will release insulin in response to external glucose concentration. The delivery device provides an erosion rate that permits an appropriate amount of insulin to be released to maintain normal glucose concentrations in a diabetic patient. With a considerably different orientation, the research on rehabilitation-exercise machines has two long-term objectives: to develop adaptive machines that can be used effectively in the evaluation and rehabilitation of muscular deficits from trauma, disuse, or disease in such diverse groups as victims of accidents and chronic musculoskeletal disorders, athletes, and the aged and to collaborate with health professionals in collecting and analyzing data provided on the capabilities of these devices that can be used to establish a data base. Thus, these machines would be versatile, incorporate active as well as passive exercise capacity, and permit investigators to collect, archive, manipulate, and compare quantitative measurements from treatment protocols. The machines would have specific capabilities that would provide orthopedists, physical therapists, and sports trainers with graded, adaptive protocols based on therapeutic goals and patient characteristics.

National Heart, Lung, and Blood Institute. The Institute supports a number of studies that may be related to, or may hold promise for rehabilitation efforts. In cardiovascular diseases, several studies have been conducted on the effects of physical exercise on hospitalized heart-disease patients, with a view toward early and safe return of patients to work. Other studies involve the development of educational and counseling programs to facilitate the recovery of cardiac surgery patients who might otherwise view physical activity as dangerous. Exercise tests and counseling techniques are used in the hospital to promote safe exercising for patients before discharge. Also, projects are under way to reduce the length of hospital stay and promote speedy return to work after heart attacks. In particular, interventions are being developed that improve in low-risk patients the confidence that they can resume their work within 3 to 5 weeks after infarction rather than the current practice of 8 to 11 weeks. These interventions include home-based exercise, stress management, and smoking abstinence programs. In lung disease, rehabilitation-related research includes the development of approaches to evaluate, in the elderly, the effects of ventilatory muscle training on ventilatory muscle endurance and overall exercise performance, studies of physical exercise training in combination with psychological counseling and health education for patients with several types of chronic lung disease, and a study of comprehensive pulmonary rehabilitation programs as compared to health education alone for determining long-term psychological and physiological effects in patients with chronic obstructive lung disease. In blood diseases, rehabilitation-related research includes several projects in sickle cell disease, such as the most efficacious approaches to individual and family counseling and patient rehabilitation. Through school intervention and counseling, sickle cell patients and their families are helped to cope with the social and emotional difficulties of chronic disease. With the aid of tutorial services, post-high school training, and occupational counseling, young adults can reach acceptable levels of academic functioning and can be oriented for occupations that are consistent with their extent of physical functioning.

National Institute of Neurological and Communicative Disorders and Stroke. In the research conducted and supported by the Institute, almost all relate to some handicapping conditions: paraplegia from head and spinal cord trauma, deafness, a crippled child with muscular dystrophy, the middle-aged aphasic stroke, the elderly with Alzheimer's disease, language disorders, and measles-induced subacute sclerosing panencephalitis, for example. Specifically, in the area of neural prosthesis, the emphasis is on attempts to achieve prosthetic neuromuscular control or sensory input of some lost neurological functions. In the area of communicative disorders, the areas of emphasis are assistive hearing devices (hearing aids, tactile devices, and auditory prostheses), assistive speech devices, and hearing and speech intervention. For hearing aids, the goals are improved performance and improved measures of the patient-instrument interface; for tactile devices, a blending of hearing, speech and language, learning, and somatosensory measures for aiding the deaf and the blind; and, for auditory prostheses, a blending of basic studies of the biocompatibility of materials with applied, clinical developments. Stroke research related to rehabilitation is concerned with remediation procedures that ameliorate specific aspects of the sensory-motor dysfunctions that are residuals of a cerebrovascular accident, particularly as useful in the development of protocols that assist recovery from cerebral injury. Relevant research programs in trauma to the central nervous system include the critical topics of intervention in acute spinal-cord injury, evaluation of urological care of spinal-cord-injured patients, behavioral recovery after brain damage, recovery and regeneration after neuronal injury, and the mechanisms and manifestations of chronic pain. In developmental neurology, relevant research includes studies of spasticity in brain-injured patients with cerebral palsy and the effect of physical therapy on cerebral palsy. For disorders of adult life, including Alzheimer's disease and other dementias, Parkinson's disease, Huntington's disease, and demyelinating and sclerosing disorders such as multiple sclerosis and amyotrophic lateral sclerosis, relevant research includes attempts to improve neurological diagnosis of spinal-cord injury and studies of the effects of a combined stress-management and EMG biofeedback relaxation techniques in patients with Parkinsonian symptoms. Other relevant topics include the development of transdermal electronics for auditory prosthesis, the feasibility of restoring function to the lower extremities by electrical stimulation, and evacuation of the neurogenic bladder.

Division of Research Resources. The Division's research related to the rehabilitation of the handicapped focuses on the causes of loss of function, ways to rehabilitate the disabled, and the use of new techniques to improve the quality of life of the handicapped. These studies include tissue regeneration and the biomechanics of disuse atrophy, memory rehabilitation in the learning disabled, and the psychosocial impact of being disabled. Devices and prostheses are being evaluated as means for maintaining function or improving the quality of life, particularly small vessels, artificial limbs, eye muscles, urinary bladder, and speech or hearing aids. Examples of recent technological research that benefit the disabled are the clinical investigation of a programmed pacemaker that operates physiologically by monitoring and pacing both the upper and lower chambers in pediatric heart patients. In addition, a new approach being investigated is the use of a diaphragm pacemaker that allows quadriplegics to breathe with both lungs. Researchers are also studying treadmill adaptation of wheelchairs for exercise and the biomechanics of wheelchair propulsion.

COOPERATION WITH OTHER FEDERAL AGENCIES

Cooperation with other Federal agencies is achieved through an interagency committee located organizationally under the Office of Special Education and Rehabilitative Services, Department of Education, which is responsible for special education expressly designed to meet the needs and develop the full potential of handicapped children and for comprehensive rehabilitation service programs designed to reduce human dependency, increase self-reliance, and fully utilize the productive capabilities of all the handicapped. These programs include research grants administered by the National Institute of Handicapped Research (NIHR), as established in 1978 by Title II of the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments (Public Law 95-602). The NIHR provides leadership and support for a national program of comprehensive and coordinated rehabilitation research. In addition, the Director of the NIHR chairs the Interagency Committee on Handicapped Research (ICHR), which is charged with coordinating rehabilitation research efforts across the Federal Government. The NIHR also submits to the Congress a long-range plan on rehabilitation research issues. The NIHR's Annual Report, submitted to the President and the Congress, summarized a study by the NIHR that, for the first time, described the core areas and cost of rehabilitation research in 28 Federal agencies. The estimate was $198 million for fiscal year 1983.

The ICHR, chaired by the Director of the NIHR, is the focal point, a resource, and a forum for Federal agencies that conduct or support rehabilitation research. The basic responsibility of the ICHR, as stated in Public Law 95-602, Section 203, is to identify, assess, and seek to coordinate all Federal policies, programs, activities and projects and plans for such programs, activities, and projects with respect to the conduct of research related to the rehabilitation of handicapped individuals. The criteria of the ICHR for identifying rehabilitation research includes identification of studies or demonstrations directed toward acquiring new or improved knowledge or the modification of existing knowledge applicable to the functional restoration, improvement, or stabilization of physical, emotional, social, academic, and (or) vocational performance and independence of physically and (or) mentally disturbed individuals. Accordingly, the ICHR, in relation to its overview responsibilities for rehabilitation-related research, serves as a mechanism for identifying all Federal agencies that conduct, fund, or sponsor research or demonstrations in the area of rehabilitation of handicapped individuals; fosters mutual understanding and appreciation of the ICHR and the member-agencies' rehabilitation research responsibilities; develops and maintains procedures for ongoing communication and exchange of information on the specific rehabilitation research programs and projects conducted or sponsored by Federal agencies; identifies research needs, overlaps, and opportunities for interagency coordination of research; develops and maintains procedures for sharing research findings and promoting the application and utilization of the knowledge; analyzes and assesses Federal efforts in rehabilitation research as a basis for cooperative planning and collaborative research; promotes interagency consultation, sharing, and exchange of individual agency resources and expertise for such essential administrative activities as policy development, design of research projects, and peer review; assists ICHR member agencies in developing research priorities as requested; and submits to the President and the appropriate committees of the Congress recommendations deemed appropriate with respect to coordination of policy and development of objectives and priorities for all Federal programs of research related to the rehabilitation of handicapped individuals.

The Director, NINCDS, is the NIH Representative to the Interagency Committee on Handicapped Research and one of the representatives of 20 agencies that have regularly attended the meetings of that Interagency Committee. Successful working relationships have been established with the National Council on the Handicapped and other groups and agencies that have an active interest in rehabilitation research. The NIHR has initiated collaborative projects with several private and Federal agencies, including the Rehabilitation Services Administration, the President's Committee on Employment of the Handicapped, the Veterans Administration, the National Institutes of Health, the National Research Council, and the Administration on Aging. The NIH will continue to participate in this effective means of coordinating and fostering Federal programs of rehabilitation-related research and of sharing and promoting its own plans for the continuation of a substantial involvement in rehabilitation-related research.

Rehabilitation-Related Research Supported by the National Institutes of Health in Fiscal Years 1984 and 1985

Institute	Number of Projects in 1984	Amount (In Thousands) 1984 (actual)	1985 (estimated)
National Institute on Aging	45	$11,533	$12,529
National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases	72	8,064	8,700
National Cancer Institute	12	2,200	2,900
National Institute of Child Health and Human Development	141	27,903	34,554
National Institute of Dental Research	19	2,729	3,100
National Eye Institute	23	2,769	2,927
National Institute of General Medical Sciences	3	544	550
National Heart, Lung, and Blood Institute	12	2,030	2,251
National Institute of Neurological and Communicative Disorders and Stroke	72	18,856	19,500
Division of Research Resources	289 *	2,066	3,111
TOTALS	688	$78,694	$90,122

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* Number of subprojects on 180 grants.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

REPORT ON THE PROCEEDINGS OF THE FIFTY-SECOND MEETING OF THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

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REPORT ON THE PROCEEDINGS OF THE FIFTY-SECOND MEETING OF THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

Executive Summary

In House Report No. 99-289, the House Appropriations Committee requested that the National Institutes of Health prepare and submit a report on the proceedings of the fifty-second meeting of the Advisory Committee to the Director, NIH. This meeting addressed the problem of obsolete biomedical research instrumentation. The Committee met on December 16, 1985. Attached to this report are a copy of the meeting agenda and a roster of invited participants.

The Committee firmly endorsed the view that the current state of biomedical research instrumentation has seriously eroded over the last ten years and that this situation is retarding the progress of biomedical research. The Committee maintained that research instrumentation was but one part of a larger issue, namely the role that the Federal Government plays in supporting the research infrastructure at our Nation's universities. The Committee was concerned with the appearance that NIH may be moving away from investing in a system of research toward the procurement of research results.

Throughout its deliberations the Committee was cognizant of the current federal budget situation, and acknowledged that NIH could only increase its support of research instruments by reducing support in other important areas. The Committee was pleased with the NIH commitment to the shared instrumentation program and felt that this program had been particularly effective.

The Committee first provided a perspective on the scope and the nature of the instrumentation problem, noting that:

- while the problem is widespread, the need for support is greatest for small instruments, those costing between $5,000 and $60,000; and

- the costs associated with maintenance and repair have risen sharply, making it extremely difficult for institutions to maintain their equipment.

In examining NIH's current efforts the Committee:

- favored keeping all current NIH instrumentation support mechanisms active and funded to the extent possible;

- supported the view that the traditional individual research project grant should be used as a principal vehicle for requesting research instrument support;

- discussed the position that institutional support grants for research instruments should be considered, recognizing that less will be done in other areas;

- asked that the NIH take action to dispel the widespread perception that NIH study sections frequently recommend deletion of funds requested for instruments on grant applications; and

- maintained that, even in the face of stringent competition for equipment funds, additional support is needed for the repair and maintenance of research instruments.

REPORT ON THE PROCEEDINGS OF THE FIFTY-SECOND MEETING OF THE ADVISORY COMMITTEE TO THE DIRECTOR, NIH

INTRODUCTION

In its report on the Fiscal Year 1986 budget for the Department of Health and Human Services, the House Committee on Appropriations stated:

> "Over the past several years, the Committee has heard testimony concerning the problem of obsolescence of research instrumentation and the inability of the universities and institutions to adequately replace and/or update instrumentation. There is concern that this obsolescence will adversely impact the future of scientific research and training. The Committee understands that the NIH Director's Advisory Committee will be addressing this issue at its December 1985 meeting. The Committee requests a report from the NIH on the proceedings of the Advisory Committee meeting." (p.38)

The following report has been prepared by the National Institutes of Health of the Department of Health and Human Services in response to this request.

BACKGROUND

The 52nd meeting of the Advisory Committee to the Director, NIH, was held on December 16, 1985. The Committee discussed the issue of biomedical research instrument obsolescence at our Nation's universities and the role that the National Institutes of Health (NIH) should play in addressing this issue. Dr. James B. Wyngaarden, Director, NIH, chaired the meeting. Several panels were organized to address the major agenda items.

This summary is not intended to be a comprehensive record of all the comments and opinions expressed at the meeting; rather, it attempts to capture the major themes and suggestions that emerged from the Committee's deliberations.

INTRODUCTION AND OVERVIEW OF BIOMEDICAL RESEARCH INSTRUMENTATION AS AN NIH CONCERN

Dr. Wyngaarden prefaced his remarks by recalling that the academic community has been concerned with this issue for over a decade. He described both past and current studies which have attempted to measure the nature and dimensions of the problem.

It was further pointed out that while the NIH has attempted to strengthen its support for research instruments, the results of a recent survey indicate that problems still exist in a number of areas. Dr. Wyngaarden questioned how NIH should respond to two key findings: one, that there is a significant shortage of smaller pieces of equipment (those costing between $5,000 and $60,000); and second, that academic institutions are particularly hard pressed to maintain and repair their current equipment.

CURRENT INSTRUMENTATION PROGRAMS AND STATUS

An overview of the diverse mechanisms through which NIH awards funds for instruments, including details on the specific types of equipment that can be awarded through different grant mechanisms, was provided the Committee. The presentation then focused on the programs and activities of the Division of Research Resources (DRR). While most of the major organizations at NIH provide support for the acquisition of biomedical research instrumentation, DRR has several programs focused specifically on instrumentation support, such as the Biomedical Research Technology Program and the Shared Instrumentation Grant Program.

The Committee reviewed trends in the types of applications submitted, the types of equipment requested, and the overall level of fiscal support provided under various programs. In comparing the level of NIH support for biomedical research instrumentation with other Federal agencies it was apparent that NIH remains, by far, the most significant source of support.

In response to questions raised earlier by Dr. Wyngaarden, it was noted that DRR does not administer a specific program directed toward supporting smaller pieces of equipment because items are provided through research project or formula grant budgets. Regarding the question of support for maintenance and technical personnel, it was stated that an expanded effort in this area could only be achieved by reducing the rate of instrument acquisition.

MAINTAINING CURRENT INSTRUMENT CAPABILITY

The discussion of the first panel was prefaced with the observation that while everyone acknowledges that there is a persistent problem with the state of research instrumentation, there is considerable variance as to the nature and the extent of the shortfall.

From the perspective of basic science departments, it was pointed out that instrument problems are most acute for young investigators attempting to set up a laboratory. The problem is also felt more deeply at small institutions. Smaller schools often lack the flexibility and scope that would allow them to apply for instruments under NIH programs which place limitations on the cost of the instruments eligible for funding.

It was suggested that investigators need greater flexibilty in the management of their grant budgets. NIH staff indicated principal investigators already have considerable leeway in controlling grant resources and that efforts are underway to examine this question further.

In discussing the differences between clinical departments and basic science departments, the Committee found little difference between the types of equipment problems faced by each. Although past survey findings have indicated that clinical departments are in better shape than basic science departments, the changing trend in the system of cost reimbursement for health care, which will reduce the flexible funds available to the chairman of the department, has obviated the advantage once enjoyed by clinical departments.

The panel discussed some of the pros and cons associated with sharing instruments. While supporting the concept of sharing, members cautioned that excessive sharing can sometimes be counterproductive to research.

The panel next took up the issue of maintaining, repairing, and upgrading instrumentation and the associated costs of these activities. Some members felt that maintenance and repair by in-house staff was limited by the increasing complexity of the instruments themselves, the cost and availability of spare parts, and the need to make a large investment in tools and training.

The final presentation of the first panel described an in-house program at NIH which rents and repairs scientific equipment used by intramural investigators. This program provides investigators with versatility in acquiring the types of equipment they need, timeliness in setting up their labs and having faulty equipment replaced or repaired, and economies which result from the lack of need for major capital investments. Since this program was started at NIH in 1974, it has grown approximately 2,000 percent. The rental program experiences a high rate of instrument utilization, suggesting that the concept of renting facilitates the sharing of research instrumentation.

The Committee raised a number of questions regarding the cost, size, and composition of the staff necessary to handle repairs on a variety of complex instruments. They also questioned whether grant funds could be used to establish similar programs for basic science and clinical departments at universities. Some members stated that such programs would only be effective at universities if investigators retained the right to use outside commercial repair services, which is one of the attractive features of the NIH program.

While some members argued that a central instrument rental and service organization would only be feasible in a large research setting, such as the NIH intramural program, other participants viewed a central maintenance and rental program as a feasible cost-saving approach, particularly helpful to young investigators just starting their research careers. Others agreed that institutions should be encouraged to provide in-house equipment support whenever possible. It was pointed out that Iowa State University has already successfully implemented a centralized equipment rental program.

Discussion led to the conclusion that instrument sharing is inhibited when the investigator who acquired the instrument realizes that other users will not assist in the maintenance and repair of the equipment they use. Some members felt that if the institution or NIH played a stronger role in ensuring that shared instruments are properly maintained and repaired, and not at the sole expense of the responsible investigator, sharing would increase.

Along with the concept of providing centralized support for equipment repair and maintenance, the view was expressed that centralized space and facilities for commonly shared devices need to be provided. An additional suggestion to enhance sharing would be to encourage study sections to recognize the need for funds for the replacement of obsolete instruments for program and-center grants, since equipment is more apt to be shared in such settings.

Dr. Wyngaarden asked the Committee to consider the consequences of increasing support for research instrumentation. Given a stable budget, any increase translates into a reduction in some other category of NIH support. It was stated that supporting personnel budgets at the expense of new, sophisticated, labor-saving devices may not be the best approach for maximizing advances in biomedical knowledge.

The Committee noted that only through the willingness of the Government and the public to invest in research has the NIH been able to achieve a position of preeminence in biomedical research. An inability to equip the researchers' laboratories adequately threatens the Nation's competitive edge.

INSTRUMENTATION SUPPORT

The next panel addressed funding for the acquisition of new instruments. A number of speakers contended that NIH study sections display a bias against requests for instrument support and that efforts should be made to reverse this bias. The NIH estimates that in FY 1985 it will award $144 million, or approximately 4.2 percent of a $3.4 billion research award base, for research instruments. The National Science Foundation projects that $270 million will be available to support equipment in FY 1987 (20 percent of its budget for research resources), while the Department of Defense estimates 10 to 15 percent of its budget for project support at universities is used for instruments. Although the NIH investment appears small in contrast to other agencies, a comparison across agencies must take into account the differing nature of research activities undertaken and the large and expensive types of equipment supported by other agencies.

The results of an internal NIH study were reviewed and cast doubt on the view that NIH study sections are not favorably responsive to requests for instruments. Some members felt that the results of the study should be widely distributed, and that NIH should work toward dispelling the current perception.

The belief was expressed that study sections not only resist recommending equipment on first-time applications but that they also are reluctant to recommend replacement of obsolescent instruments on previously funded grants. The Committee felt that the only time study sections are eceptive toward allowing a principal investigator to refurbish out of date equipment is when a competing renewal is submitted. If indeed there is a trend toward longer grant awards, there will be even less opportunity to replace obsolete instruments. It was proposed that the advisory councils do more toward ensuring that equipment requests receive appropriate consideration.

Present day instrumentation continues to change rapidly as new emerging technologies are incorporated into current equipment. Although these advances improve the capabilities of new devices, the trade off is that increasingly complex instruments are increasingly more expensive to maintain and repair. These increasing costs have outstripped both inflation and the growth of NIH grant support.

The panel argued that biomedical researchers cannot expect their hard-pressed institutions to close the instrumentation gap, nor can they expect industrial or philanthropic support to help. Improving management practices at universities may help in some minor ways. In the end, NIH stands as the single most important resource that will be looked upon to stem the growing instrumentation shortfall.

The contention that the problem is most acute for new rather that established investigators was challenged. It was stated that new investigators represent only a small portion of the broader research effort and that NIH study sections may incorrectly assume that established investigators' laboratories, which have received equipment in the past, are equipped capably. It was suggested that equipment amortization be incorporated into awards so that as instruments become obsolete funds would be available for upgrading or replacement.

It was suggested that the instrument problem may be part of a larger issue, namely the role that the Federal Government plays in the support of biomedical research. As expectations increase to broaden that role, for example by expanding the scope of support underpinning the emerging biotechnology industry, additional pressure may be felt in the instrumentation area. In addition, the perception of some that the research system has moved from an investment in creativity to the procurement of research results may be contributing to the problems in this area.

As in the first panel, discussants concurred with the suggestion that NIH should play a stronger role in supporting the efforts of grantee institutions to establish centralized service and support facilities.

NIH INITIATIVES FOR INSTRUMENTATION SUPPORT

The last panel opened with a description of a common situation in which one investigator with several grants, or a small group of investigators each with one grant, cannot justify a piece of equipment which could support several projects yet cannot be justified under any one single grant. Further, the cost of the instrument places it below the $100,000 limitation of the Shared Instrumentation Grant Program (SIG) of the Division of Research Resources.

One approach to this problem would be to relax the restriction under the SIG program. Another solution would be to establish a separate program specifically designed to meet this need. A Small Instrumentation Grants proposal was outlined for the Committee. This proposed program would be geared specifically to supply instruments that would support research on a variety of grants that have previously been approved and funded, and would allow for a somewhat different review process.

The next discussion indicated that it is extremely difficult for study sections to assess the real level of instrumentation need tied to a given application. It was suggested that study sections should base their recommendations on the scientific credentials of the applicants rather than attempting to determine the relative level of need for research instruments within the context of the research goals.

A pilot program initiated by one of the major divisions of the National Institute of Arthritis, Diabetes, Digestive, and Kidney Diseases was described. This program provides support for instruments costing between $5,000 and $50,000 which cannot be justified on a single traditional individual research project grant. The response to the program, which was begun in 1984, has been significant. A key concern surrounding the program centered upon the administrative cost burden attendant to submitting the applications and the subsequent review process. It was determined that the program is feasible as long as sufficient funds are available to allow for a reasonable award rate.

The issue from the perspective of a university president was addressed next. One of the major reasons universities are so concerned with the quality of the research infrastructure is their fear that they will no longer be able to attract and retain talented faculty. The need to maintain current equipment, added to the cost of setting up laboratories for the next generation of investigators, has placed enormous pressure on the capital budgets of universities. Cost-sharing schemes, attractive to many as a way of stretching research dollars, have ultimately an extremely disruptive effect on university budgets, create conflict between the prospective grantee and the university administration, hamper the university's ability to develop long range budget plans, and result in an unequal distribution of funds.

A suggestion was presented that a national, integrated funding pattern be established through an institutional awards program for instruments costing between $5,000-$60,000. Such a program would have to be both reliable and substantial. It would place the responsibility for the review of projects at the institution and would thereby reduce the funding agency's administrative costs. These institutional awards would have to take into account instrument maintenance, repair, and operating costs. It was explained that this proposed mechanism derives from the fact that funding agencies rarely account for the unseen costs associated with research equipment after the award is made. It was suggested that the university infrastructure may be damaged as universities struggle to cover these ancillary expenses.

Other members questioned this proposal saying that an institutional awards program would place another administrative and bureaucratic burden on the investigator. Further, some members expressed reservations over the use of formula based funding approaches.

In the discussion that followed, Dr. Wyngaarden asked the Committee to review the options that had been suggested over the course of the day, recognizing that an increase of support in one area results in a reduction in some other area.

Some members articulated that the first priority should be to provide equipment which would allow a group of investigators to use a technology that they otherwise could not use; second, that the individual research project grant mechanism should be preserved; and third, that obsolescent research equipment should be replaced. It was pointed out that as some older equipment becomes technologically obsolete, there should be less emphasis placed on replacing it with a similar device when entirely new technologies are on the horizon.

A number of discussants urged that applicants should not refrain from including requests for instruments on grant applications when they feel that the equipment is really needed. Although this may not result in more resources, at least a more accurate picture of instrument needs would emerge and these needs could be woven into the overall review process.

Members also placed emphasis on the fact that instruments awarded on grants belong to the institution and not the principal investigator and that every effort should be made to insure that equipment requests are only submitted when instruments are really needed.

CONCLUDING REMARKS

In summarizing the meeting, Dr. Wyngaarden characterized the discussion as representing another aspect of the overall concern that the extramural awards system may have over the years moved from an investment in creativity toward the procurement of research results. He further observed that the Committee and participants had identified a number of factors in the funding of instruments that is a facet of a larger issue, namely a shift towards greater accountability during a period of time when total resources are constrained and research opportunities abound. Given these factors, an increase in the sense of stewardship on the part of initial peer review groups and research managers is understandable. However, in the process of making the available research dollar go as far as possible, perhaps these efforts have reached the point of becoming counterproductive in some areas.

Dr. Wyngaarden stressed that NIH must not lose sight of the fact that successful pursuit of its mission requires heavy dependence upon extramural institutions. Therefore, the NIH must be concerned with the welfare of extramural institutions and avoid excessive use of cost-sharing schemes that could play havoc with university capital budgets. Dr. Wyngaarden again reminded the Committee that any adjustments for funding instruments would involve trade-offs in other areas; however, he did feel that improvements could be made in the utilization of central rental, repair, or sharing arrangements.

The concern that efforts should be made to encourage grant applicants to include requests for equipment on individual research project grants and to dispel the perception that they will antagonize study sections with such requests was supported by Dr. Wyngaarden. He suggested that advisory councils should play a more forceful role in influencing the manner in which study sections regard requests for instruments.

The Committee was thanked for their views and given assurance that the substance of their deliberations would be analyzed fully and carefully.

AGENDA

52nd Meeting of the Advisory Committee
to the Director, NIH

December 16, 1985

Building 31, C Wing, Conference Room 10
National Institutes of Health
Bethesda, Maryland

BIOMEDICAL RESEARCH INSTRUMENTATION

MORNING SESSION

9:00 Introduction . . . . Dr. Wyngaarden

9:05 Status Report on Activities and
Considerations Concerning NIH's Role
in Fostering the Nation's Leadership
in Biotechnology--Follow-up on June 24-25
DAC Meeting . . . . Dr. Kirschstein

9:20 Overview of Biomedical Research
Instrumentation as an NIH Concern . . . . .Dr. Wyngaarden

9:35 Current Instrumentation Status . . . . Dr. Pickett

10:00 Coffee Break

10:15 Maintaining Current Instrument Capability

Chairman. . . . . .Dr. Raub

Speakers

- Obsolescence and Replacement
  of Current Research Instrumentation
  - Basic Science Departments. . . . . Dr. Guyton
  - Clinical Departments . . . . Dr. Kipnis
- Maintenance and Repair of
  Instrumentation . . . . .Dr. Cox

General Discussion

11:30 Lunch

AFTERNOON SESSION

1:00 Instrumentation Support

Chairman. Dr. Alexander

Speakers

- Initial Review Group Study of R01 Instrumentation Requests . . . . Dr. Sherman
- National Institute of General Medical Sciences Advisory Council Concerns . . . . Dr. Chapman
- Investigator's Point of View . . . . . . .Dr. Dallos

General Discussion

2:15 NIH Initiatives for Instrumentation Support

Chairman. . . . . Dr. Merritt

Speakers

- Small Grants Proposal. . . . . .Dr. Bartlett
- The NIADDK Activity. . . . . Dr. Johnson
- An Institutional Approach. . . . . Dr. Handler

General Discussion

3:30 Concluding Remarks and Adjournment. . . . . . .Dr. Wyngaarden

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RETT SYNDROME

Thomas E. Malone

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Deputy Director, NIH

February 1986

RETT SYNDROME

INTRODUCTION

In House Report No. 99-289, the Appropriations Committee requested that the National Institute of Child Health and Human Development, in collaboration with the National Institute of Neurological and Communicative Disorders and Stroke, prepare a special report prior to next year's hearings on Rett syndrome. Specifically the Appropriations Committee stated:

> "The report should include an evaluation of the feasibility of support for a coordinated research program in a Multidisciplinary Center, with emphasis on genetics, neurophysiology, neuropathology and neurochemistry as needed. The goal would be to identify genetic markers, and to learn how this baffling and progressive neurological dysfunction comes about."

The following report has been prepared by the National Institutes of Health of the Department of Health and Human Services in response to this request.

BACKGROUND

The original article on the Rett syndrome was published in the German literature in 1966 by Dr. Andreas Rett from Vienna who described 22 girls with a progressive neurological disorder and characteristic constant hand movements. Because of the relatively restricted circulation of the original article, the medical and scientific communities were unaware of the disorder until 1983 when a Swedish physician published in the English literature a review of 35 girls with the syndrome. There is now a general consensus that the Rett syndrome represents a distinct disorder. Following normal development until age 6-12 months, affected girls experience a plateau in their progress follwed by regression of psychomotor function. They exhibit autistic-like behavior, characteristic hand movements consisting mainly of hand clapping and hand washing, loss of purposeful use of the hands, diminished expressive abilities, avoidance of eye contact, a lag in head growth, and seizures.

The prevalence of Rett syndrome has been estimated to be about 1 in 15,000 girls and the condition has been reported in all races and in all parts of the world. To date, 600 cases have been identified. Two pairs of sisters, a pair of half-sisters from the same healthy mother and a pair of twins (presumably identical) have been reported to have the syndrome. The condition has not been found in males. Although this suggests an X-linked dominant pattern of inheritance which is lethal to males, the precise genetic transmission will be difficult to confirm because affected girls are unlikely to bear children. Due to the relatively recent indentification of this disorder, life expectancy for affected patients is uncertain, but physicians believe that if it is shortened, it will be as a result of complications from increasing disability and incapacitation rather than the intrinsic disease.

The cause or the pathogenesis of Rett syndrome is unknown. Biochemical, cytogenetic and cytologic evaluations have been reported to be normal. Radiographic and neuropathologic studies of the brain have shown cortical atrophy (shrinkage) in some patients. Abnormalities in the electrical activity of the brain have been described in a number of cases. Significantly reduced levels of certain neurotransmitters which modulate the neuronal activity in the brain and spinal cord, particularly those which regulate and control voluntary movements, have been reported. These observations may help to elucidate the basic underpinnings of some of the clinical manifestations in Rett syndrome. In the absence of a characteristic biochemical or genetic marker by which the diagnosis of Rett syndrome can be confirmed, it is not now possible to delineate the range of clinical variation.

ACCOMPLISHMENTS

The Rett syndrome represents a biologically-based behavioral disorder and provides an opportunity to learn more about the neurological bases of behavioral disturbance. In order to update knowledge of the condition, the National Institute of Child Health and Human Development (NICHD) and the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) co-funded the Second International Workshop on Rett Syndrome at the John F. Kennedy Institute of the Johns Hopkins Medical Institutions in Baltimore in November 1985. Invited participants ~~from all~~ over the world addressed the epidemiological, clinical, neuropathological, biochemical, neurophysiologic, neuroimaging, pathogenetic, and genetic aspects of the condition. The scientific meeting was followed by a conference attended by clinicians and professionals in the behavioral sciences, special education and other health-related fields in order to disseminate information and suggest approaches to therapy and management. A final session was attended by parents during which counseling and management were discussed.

PLANNED ACTIVITIES

The various mechanisms that are currently used by the National Institutes of Health to support research, research training, and conferences adequately address and accommodate the types of research that are required for a better understanding of the cause, pathogenesis, and other aspects of Rett syndrome. An example of what has already been achieved is the second international conference held recently in Baltimore. Staff of the NICHD and NINCDS attended that conference and encouraged investigators to submit grant applications for research on Rett syndrome. Another example is a program announcement by the NINCDS, published on July 18, 1985, in the NIH Guide for Grants and Contracts, encouraging submission of research center grant applications to establish multidisciplinary research centers for the purpose of investigating epidemiologic, genetic, biochemical and clinical aspects of neurogenetic disorders of infancy and childhood and of developing measures for their prevention, early diagnosis, and treatment. Responses to this announcement have been received and are presently under review.

Given the current state of knowledge about Rett syndrome and the relative rarity of the disorder, staff of the two Institutes believe that research on Rett syndrome would best be conducted either in such a center in conjunction with multidisciplinary studies of other relatively rare neurogenetic disorders, or through individual research grant applications on various aspects of Rett syndrome, as encouraged by both Institutes.

REPORT TO THE
HOUSE APPROPRIATIONS COMMITTEE
ON
THE LEVELS OF SERVICE PROVIDED
TO SOCIAL SECURITY BENEFICIARIES
AND
THE PUBLIC IN GENERAL
FOR QUARTER ENDING
DECEMBER 1985

Report 1
Social Security Administration
March 1986

Report 1

REPORT TO THE HOUSE APPROPRIATIONS COMMITTEE ON THE LEVELS OF SERVICE PROVIDED TO SOCIAL SECURITY BENEFICIARIES AND THE PUBLIC IN GENERAL

REPORT 1, DECEMBER 1985 QUARTER

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REPORT TO THE HOUSE APPROPRIATIONS COMMITTEE ON THE LEVELS OF SERVICE PROVIDED TO SOCIAL SECURITY BENEFICIARIES AND THE PUBLIC IN GENERAL

REPORT 1, DECEMBER 1985 QUARTER

INTRODUCTION

In House Report No. 99-289, accompanying the Department of Health and Human Services Appropriation bill for 1986, the House Committee on Appropriations directed the Commissioner of Social Security to develop a report with indicators that measure the level of service provided to Social Security beneficiaries and the public in general. The following language was contained in the Report:

> The staffing and facilities issues have brought into focus the concern of this Committee and the Congress as a whole that levels of service be maintained for Social Security beneficiaries and the public in general. In order to better evaluate the effect of changes in Social Security's administrative activities on service, it is essential that the Committee have dependable data on what is happening in the field. This includes regional and national average processing time for processing new or revised claims, posting of earnings or appealing decisions; the accuracy of payments as measured by existing quality control programs; and finally the convenience to the public as measured by commuting and waiting times, etc. The Committee therefore directs the Commissioner to develop a report on these measures by January of 1986 and to submit this data to the Committee quarterly for at least the next two fiscal years. In this manner both SSA and the Congress should be able to evaluate the impact of any changes which may be made in staffing, field structure, data processing or telecommunications.

This first report, responding to the Committee's request, provides information for the December 1985 quarter and includes data currently available in Social Security systems and records. Data on waiting time, and commuting time as appropriate, will be provided beginning with the March 1986 quarter. While management, at the local level, has informally monitored waiting time and commuting time in Social Security offices, SSA has not formally collected on an ongoing basis regional and national data on waiting time or commuting time. Information on waiting times is being obtained through a series of studies which began in January 1986 and will be included in all subsequent reports. The formats for reporting this information have been included and can be found on pages 23 and 24. For comparison purposes, summary graphs have been provided for all data in this report. These graphs can be found beginning on page 25.

Over the past 50 years, SSA has consistently made efforts to improve the service it provides to the public. Every effort is made to provide good service to the public in the most efficient and cost-effective manner because SSA's administrative costs are paid from the Social Security Trust Funds. In recent years, we have kept the costs of administering the Retirement, Survivors and Disability Insurance programs to about 1.3 percent of contributions. It is significant that of the four basic values which we have enunciated underlying SSA's public service mission, three specifically deal with providing good service in a cost-effective manner. These values are : 1) provide timely and accurate benefit payments, 2) administer SSA's programs efficiently and effectively, and 3) provide courteous, sensitive and dignified public service.

The public gave SSA high marks on quality of service according to the January 1986 General Accounting Office (GAO) survey of randomly selected beneficiaries. Most of the respondents had recent contacts with SSA and were asked to rate service and comment on such things as courtesy, privacy of offices, clarity of program explanation and waiting time for service. Overall, four out of five persons rated SSA service good to very good and over half of those surveyed rated SSA services better than the service they receive from other Government agencies. According to the GAO report, "Most OASDI and SSI clients who visited SSA field offices waited no longer than they had expected for service and had enough privacy to conduct their business. Those who visited or reached SSA by telphone found SSA employees very courteous and clear in explaining the programs and rules, generally were satisfied to very satisfied with the amount of time it took to complete their business, and believed that SSA did a good to very good job in handling the purpose of the contact." Currently, we are exploring various approaches to conducting the ongoing client surveys which GAO recommended in its report. In addition, data on waiting time are being collected for the quarterly reports to the Committee. These data, along with data from the ongoing surveys of client satisfaction with SSA service, will provide the information on the quality and convenience of SSA service as requested by the Committee.

In addition to the GAO report on the service SSA is providing, the Agency has seen a number of recent accomplishments which directly relate to improved service:

- Reduced processing time for Retirement, Survivors and Health Insurance claims to 21 days, and for SSI aged claims to 11 days.
- Reduced the time it takes to issue a Social Security card to 11 days.
- Reduced field office computer response time to under 3 seconds, providing the public with quicker responses to inquiries.
- Provided immediate computer access to computation of benefit amounts with an anticipated increase in the accuracy of payments.
- Converted magnetic tape files to direct access storage devices, sharply reducing errors, and the time it takes to respond to inquiries.
- Eliminated the 4-year backlog in the Automated Earnings Reappraisal Operation process that existed a few years ago.
- Expanded the online data base to allow field offices to provide immediate benefit estimates for people age 60 and over.
- Reduced the number of pending cases.
- Improved the language in beneficiary notices to make them clearer and more easily understood.

- o Maintained the Retirement and Survivors Insurance accuracy rate at 99.5 percent.
- o Improved the payment accuracy rate for SSI aged claims to 96.7 percent.
- o Increased the disability decision accuracy rates for initial title II and title XVI claims to 96.3 percent.

A great deal of concern has been expressed about SSA's staffing reduction plans as well as the impact of systems improvements on staffing. While SSA is striving to improve productivity and achieve resource savings, these objectives are not being pursued at the expense of service to the public. It is significant that SSA received such a positive reaction from claimants, as reflected in the GAO report discussed earlier, yet SSA full-time equivalents (FTE's) will have declined 7.7 percent from FY 1983 through FY 1986. At the same time, SSA has seen improved overall processing time and quality.

PROCESSING TIMES - INITIAL CLAIMS

The Committee has requested regional and national average processing time for new claims. The following charts (Charts I and II) contain average overall processing time in days for the major Social Security claims workloads. These include:

- o title II claims for retirement, survivors and health insurance (RSHI);
- o title II claims for disability (DI);
- o supplemental security income aged claims (SSIA); and,
- o supplemental security income blind/disabled claims (SSIBD).

The RSHI and DI data are derived from the Social Security Administration (SSA) Management Information Initial Claims Record System and include all initial claims for retirement, survivors, disability and health insurance. The numbers reflect mean processing days for all claims cleared in the quarter for which the report is issued.

"Processing time" is defined as the mean of the number of days from the date of the application to the date of the allowance or denial decision. Disability processing time includes the period of time during which the case is in the Disability State Agencies for disability decision.

The SSIA and SSIBD data are derived from the Supplemental Security Income Initial Claims Report System. Overall processing time includes the mean of all initial claims for aged, blind and disabled Supplemental Security Income. The numbers reflect mean processing days for all claims cleared in the quarter for which the report is issued. SSIBD processing time includes the period of time during which the case is in the Disability State Agencies for disability decision.

Chart I contains, for comparison purposes, national overall processing time for the December 1985 quarter as well as the December quarters for the previous 2 years. Chart II contains regional processing times for the December 1985 quarter.

Chart I indicates continuing improvement in the processing time for retirement, survivors and health insurance claims. SSI aged claims have basically stabilized at around 11 days. The higher figures for title II disability claims and SSI blind and disabled claims in the December 1985 quarter, as compared to the September 1985 quarter, reflect an anticipated increase in processing time as a result of the implementation of the 1984 disability legislation.

Variations among regions in the processing of workloads have always existed and are the result of a variety of factors, including client characteristics, socioeconomic conditions, the relative performance of Disability State Agencies, geographic area served, etc. In some instances, variations can be caused by the law. An SSI claim, for example, is a much more difficult work unit in States with supplemental benefits and complex living arrangement situations than in those States which do not include those legal conditions.

Chart I

MEAN PROCESSING TIMES, CLAIMS
QUARTERLY REPORT
DECEMBER QUARTER, 1985

National Processing Times in Days

	December Quarter, 1983	December Quarter, 1984	September Quarter, 1985	December Quarter, 1985
RSHI	23.8	22.9	21.4	20.7
DI	68.6	71.3	66.0	71.2
SSIA	17.6	14.5	10.8	10.9
SSIBD	71.8	70.7	57.7	64.7

MEAN PROCESSING TIMES, CLAIMS
QUARTERLY REPORT
DECEMBER QUARTER, 1985

Chart II

Regional and National Mean Processing Times in Days - December Quarter 1985

	BOS	NY	PHI	ATL	CHI	DAL	KC	DEN	SF	SEA	National
RSHI	26.5	22.3	16.8	20.3	17.7	23.2	19.5	21.5	20.3	19.5	20.7
DI	82.1	102.4	48.6	63.8	75.9	68.0	61.6	66.8	76.6	64.3	71.2
SSIA	11.4	13.4	9.4	13.0	8.0	10.5	10.9	10.2	9.7	8.9	10.9
SSIBD	67.5	95.5	54.7	61.0	61.7	59.5	46.4	59.9	69.0	55.3	64.7

PROCESSING TIMES - APPEALS

The Committee has requested regional and national average processing time for claims in the Appellate process. The following (Chart III) indicates processing times for Disability Insurance (DI) reconsideration requests and all hearing requests.

Reconsiderations are the first step in the appeals process whereby a claimant requests that a decision (usually a denial) be reviewed. Chart III includes data on processing times for DI reconsiderations only; other reconsideration times are not available. The source for this data is the SSA Management Information Initial Claims Record System. Processing time for reconsiderations is the mean of the number of days from the date of the reconsideration request to the date of the reconsideration decision. The data shown on Chart III reflect processing times for all DI reconsiderations on which final decisions have been made in the quarter for which the report is issued.

Hearings are the second step in the appeals process whereby the claimant requests that an unfavorable reconsideration decision be reviewed by an Administrative Law Judge. The data in Chart IV are derived from the Office of Hearings and Appeals Case Control System. The processing times for hearing cases include Continuing Disability Review (CDR) cases and hearings requests on title II and title XVI initial claims and postentitlement actions. Also included are processing times for Appeals Council and District Court remands that are returned to an Administrative Law Judge for additional evidence or reconsideration, etc. The processing times for these cases are measured from the date of the Appeals Council or Court remand order. Other cases are measured from the date of the request for hearing until final dispensation.

Information for prior periods has also been provided on a national level for purposes of comparison on Charts III and IV. The higher December 1985 quarter figure for disability reconsiderations reflects an expected increase in processing time as a result of implementation of the 1984 disability legislation on mental impairment cases.

Chart III

MEAN PROCESSING TIMES, DI RECONSIDERATIONS
QUARTERLY REPORT
DECEMBER QUARTER, 1985

National Processing Times in Days

	December Quarter, 1983	December Quarter, 1984	September Quarter, 1985	December Quarter, 1985
DI Recons.	50.3	50.6	50.7	56.6

Regional Processing Times in Days

	BOS	NY	PHI	ATL	CHI	DAL	KC	DEN	SF	SEA	National
Quarter Ending 12/85	73.1	86.2	41.8	45.5	59.1	48.9	59.4	53.3	65.6	54.2	56.6

Chart IV

MEAN PROCESSING TIMES, HEARINGS
QUARTERLY REPORT
DECEMBER QUARTER, 1985

National Processing Times in Days

	December Quarter, 1983	December Quarter, 1984	September Quarter, 1985	December Quarter, 1985
Hearings	184	168	160	154

Regional Processing Times in Days

	BOS	NY	PHI	ATL	CHI	DAL	KC	DEN	SF	SEA	National
Quarter Ending 12/85	143	135	159	139	161	159	155	162	168	197	154

WORKLOADS PENDING

Workloads pending final disposition have an effect on the overall time required to process claims and other beneficiary actions. During fiscal years 1984 and 1985, the total value of work pending in SSA's major operating components remained nearly constant after decreasing about 25 percent from the fiscal year 1983 level. However, during the first quarter of fiscal year 1986, a significant increase occurred in disability claims workloads, while the pendings for many other major workloads declined below the level achieved at the end of FY 1985. As explained in the fiscal year 1987 budget justification (page 166), 185,000 mental impairment cases denied since enactment of P.L. 98-460 in October 1984 are to be reviewed again under new rules for evaluating mental impairments. During the first quarter, training was conducted and each Disability State Agency was evaluated to make certain that the new evaluation criteria would be understood and uniformly applied. Processing of those disability cases was delayed; they were retained in the district offices pending completion of the training and Disability State Agency validation process based on new regulations pertaining to mental impairment cases which were published in August 1985. It was decided that this delay was warranted to ensure correct processing of these cases in accordance with the 1984 Amendments. Those cases are being processed now. After this temporary backlog is eliminated, the claims pending are expected to return to approximately the same level experienced during fiscal year 1985. The small increase in the pending level of certified earnings records is an insignificant seasonal variation.

Chart V

Workloads Pending

	FY 1984	FY 1985	December 1985 Qtr.	Percent Change from FY 1985
Field Offices				
RSHI claims	151,400	155,400	118,800	-23.6
DI claims	260,000	233,400	275,800	+18.2
SSI aged claims	12,500	6,100	3,900	-36.1
SSI blind and disabled claims	169,000	217,500	263,400	+21.1
RSHI and SSI overpayments	122,400	86,000	83,000	- 3.5
Program Service Centers				
RSHI claims	91,800	85,600	60,700	-29.1
Overpayments	54,600	30,600	23,300	-23.9
Office of Disability Operations				
DI claims	48,500	35,600	30,500	-14.3
Office of Central Records Operations				
Certified wage records for RSHI and DI claims	85,800	58,400	65,700	+12.5
Office of Hearings and Appeals				
Hearings	107,800	107,600	91,400	-15.1

Abbreviations found in Chart V

- RSHI - Retirement, Survivors and Health Insurance, title II
- DI - Disability Insurance, title II
- SSI - Supplemental Security Income, title XVI

POSTINGS OF EARNINGS

The Committee requested data on the postings of earnings to a wage earner or self employed person's individual account. The following indicates the current status of wage record postings as of the December 1985 quarter.

- SSA has completed the processing of Tax Year 1984 annual wage reports. 1985 annual wage reports are currently being filed and will be posted and reported in future quarters.

- As part of the 1985 postings process, 175.5 million 1984 wage items have been posted to employee earnings records.

- In 1982, there was a 39 month backlog of uncredited earnings. This backlog has been eliminated and wages are now credited to the proper earnings record within 9 months of receipt. The goal is to reduce this time further.

- For the tax year 1985 wage reporting cycle - starting this spring - SSA plans further improvements in processing of wage items including posting wages weekly rather than quarterly.

- Beneficiaries who work after retirement may be due increases in their benefits because of additional earnings. The improved wage posting operation has resulted in over 2 million beneficiaries with additional earnings receiving the benefit increases to which they are entitled without the delay experienced in the past.

- It is anticipated that the timeframes for the posting of earnings will be greatly reduced as a result of the initiative to increase the use of magnetic media for reporting wages rather than paper W-2 forms. For tax year 1984, the number of wage items reported by employers via magnetic media increased by nearly 9 million. For tax year 1985, it is estimated that 8 million more records will come in on magnetic media. Regulations proposed by IRS requiring certain employers to report on magnetic media should substantially reduce the wage reports we receive on paper.

- Because of the improvements in wage reporting, the discovery and prevention of overpayments has been significantly enhanced.

ACCURACY

The Committee requested information on the accuracy of payments as measured by existing quality control programs. SSA collects accuracy data in two broad areas:

1. One is the accuracy of payments for retirement and survivors insurance program (RSI), and for Supplement Security Income payments (SSI).
2. The second area involves the accuracy of the disability decisions made in Disability State Agencies.

The following sections deal with these two areas of accuracy.

PAYMENT ACCURACY

The SSA Quality Review system is designed to provide statistically reliable information on how well the programs administered by the Social Security Administration (SSA) are operating. Each month a random sample of cases is selected and reviewed. The data from these reviews provide program administrators with:

- Information regarding the accuracy of program dollar payments;

- Information on the adequacy of Agency adjudicative processes that serves as the basis for recommendations for improving procedures and instructions, modifying policies and strengthening program administration.

These data are collected by two separate and distinct quality review systems. The focus of the Payment Review System is the overall accuracy of payments made by the programs. The focus of the Process Review System is adjudicative accuracy and measures the current adherence of operating components to program policies and procedures.

Statistical data from payment accuracy and process reviews are analyzed to arrive at an overall picture of program accuracy. Statistical data are analyzed in the light of other available information to identify error trends as well as major types and causes of error. This information is then utilized to forecast future error rates and to identify areas for corrective action.

Payment Quality Review System - A sample of the payments made is selected for review and all eligibility and payment factors are redeveloped to determine:

- o payment accuracy;
- o causes of incorrect payments;
- o why incorrect payments occur; and,
- o responsibility for incorrect payment (recipient or Agency).

Through a random sample of cases on the rolls, the payment review sample provides information on the accuracy of SSI and RSI payments and management information as to types and causes of errors.

The RSI payment sample (Chart VI) consists of an annual random sample of 2,000 cases selected from current payments. Each case represents one Social Security account number and all persons who are receiving benefits on that account. The SSI payment sample (Chart VII) consists of an annual random sample of 16,000 cases from current payments. The sample of SSI cases is considerably larger because of the nature of the program. Considerable change in beneficiary circumstances as well as the numerous factors which affect eligibility or benefit amounts are a part of this and other needs-based programs. Therefore, a much larger sample is required to monitor the accuracy of both federal and State SSI payments.

Eligibility factors are verified through direct contact with the beneficiary and collateral contacts to verify eligibility-related factors. After all the required eligibility/payment proofs are obtained, a payment accuracy determination is made. In instances where it is determined the person received an incorrect amount of benefits, benefit levels are corrected and additional decisions are made as to why the incorrect payment occurred.

The results of the review are transmitted to the Quality Assurance computer system to generate statistical data. The data are analyzed to identify trends and to develop recommendations to improve future payment accuracy.

Chart VI

RSI PAYMENT ACCURACY

Year	Percentage of Dollars Paid Accurately
1981	99.5%
1982	99.6%
1983	99.5%
1984	99.5%
1985	99.5%

Total beneficiaries as of December 1985: 33.1 million

The Retirement and Survivors Insurance (RSI) payment accuracy has remained relatively stable over the past five years. The basic factors affecting entitlement are age and lifetime earnings. Age records now exist for virtually all of the population and earnings are reported annually to SSA by employers. After entitlement, factors that can affect payment are, the annual earnings test for those beneficiaries working, and recomputations of benefit rates which are often required.

Chart VII

SSI PAYMENT ACCURACY

Period	Percentage of Dollars Paid Accurately
10/81 - 03/82	95.2%
04/82 - 09/82	95.9%
10/82 - 03/83	95.9%
04/83 - 09/83	96.4%
1984 (10/83 - 09/84)*	96.7%*
1985 (10/84 - 09/85)**	96.7%**

Total beneficiaries as of December 1985: 4.1 million

*The sample was reported on a six month basis through FY 1983 and was moved to an annual basis beginning FY 1984.

**Preliminary figure--final figure to be available by end of March 1986.

The SSI payment accuracy rate for the last fully completed period (FY 1984) is 96.7 percent. Preliminary data for the latest period indicate the accuracy rate has remained at 96.7 percent. Final data should be available within the next 30 days. These rates reflect a steady upward trend in SSI payment accuracy and represent the highest payment accuracy ever attained for the SSI program. The increase in payment accuracy can be attributed to a number of causes, including successful identification of high error prone case categories and strategies to correct the error causes, automatic matching operations, and improved field office interviewing and case processing techniques.

Process Review System - Through a random sample of newly entitled beneficiaries, the process review system provides information on the accuracy of current adjudication of SSI and RSI initial claims and management information as to the types and causes of error.

The Retirement Survivors Insurance sample currently consists of 57,500 cases annually and the SSI sample currently consists of 48,000 cases annually.

Each sample case receives an intensive review of all casefile documentation related to the initial claim. The casefile is reviewed to determine the adequacy of documentation and adjudicative decisionmaking measured against applicable program policy and procedural requirements.

The results of the review are transmitted to the Quality Assurance computer system to generate statistical data. The data are analyzed to identify trends and to develop recommendations to improve future processing activities. Recommendations are reported to the appropriate policy and operating components on a regular basis.

Chart VIII

RSI PROCESS ACCURACY

Quarter Ending	Percentage of Cases Paid Accurately
03/85	96.8
06/85	97.3
09/85	97.3
12/85	96.9

RSI Process Trend Analysis - RSI process accuracy for initial claims has remained relatively stable for 1985. These rates represent the numbers of cases which are free of dollar error.

Chart IX

SSI PROCESS ACCURACY

Quarter Ending	Percentage of Cases Paid Accurately
03/85	97.2
06/85	98.0
09/85	98.2
12/85	98.1

SSI Process Trend Analysis - SSI process accuracy for initial claims has increased slightly for calendar year 1985. Major improvement was noted in the 06/85 quarter, followed by an increase in accuracy in the 09/85 quarter to an accuracy rate of 98.2 percent. The rate remained stable in the 12/85 quarter at 98.1 percent. These rates represent the number of cases which are free of dollar error.

DISABILITY QUALITY ASSURANCE

Title II and title XVI disability determinations are made by Disability State Agencies under authority of section 221 (a) of the Social Security Act. The Act provides that States must make disability determinations in accordance with the standards and criteria contained in the law and regulations and in other written guidelines of the Secretary. The Act also provides that the Secretary shall promulgate regulations specifying performance standards, including the rate of accuracy of decisions.

Initial decisions are the decisions as to whether a claimant meets the disability requirements to receive benefits when the claim is initially filed. The reconsideration decision is a review of the initial determination. In the vast majority of cases it is a denial of benefits at the initial level which is being appealed by the claimant. Both decisions are rendered in Disability State Agencies.

Section 221 of the Act provides the statutory basis for Federal quality reviews of State disability determinations. The Social Security Administration conducts the quality assurance (QA) reviews in the 10 regional disability quality branches (DQB).

An ongoing random selection of each State Agency's cases, both title II (DI) and title XVI (SSI), is routed to the DQB after the State Agency decision but before the release of the notice to the claimant. The DQB review involves a complete examination of the casefile including an independent review of the medical evidence by Federal physicians. Cases with deficiencies which affect the outcome of the payment decision or amount of benefits are returned to the State Agencies for correction.

The measure of the quality of State Agency adjudication is the QA accuracy rate. The accuracy rate is the percentage of QA cases reviewed in which the casefile establishes that the State Agency correctly awarded or denied benefits for an initial claimant or correctly ceased or continued benefits for a beneficiary. Inaccurate cases include State Agency decisions which should either be: a) reversed based on the existing casefile evidence; or, b) further documented because the Federal reviewer cannot determine whether payment or nonpayment of benefits is appropriate.

For purposes of comparison, accuracy data for prior periods have been provided. Quarterly data have been supplied for initial decisions; however, reconsideration data are presently available on a semiannual basis only. The reconsideration accuracy data are produced every 6 months, but are based on 12 months of data.

Chart X

DI PROCESS ACCURACY

Initial Disability Claims

Period	Percentage of Cases With No Decisional/Documentation Errors
03/85 Quarter	96.1
06/85 Quarter	96.0
09/85 Quarter	96.3
12/85 Quarter	96.3

Reconsiderations

07/83-06/84	94.1
10/83-09/84	94.2
04/84-03/85	94.7
10/84-09/85	95.4

Total Disability Insurance Beneficiaries as of December 1985: 3.9 million

WAITING TIMES AND COMMUTING TIMES

The Committee has requested that SSA provide it with indicators of convenience to the public of its facilities as measured by commuting and waiting times.

In January 1986, SSA field offices nationally began collecting data on waiting times in Social Security offices for purposes of this report. These data will be included in the March 1986 quarterly report.

Regions will also collect data on commuting times before and after changes in field facilities. These data will be included as appropriate in this report as facility changes occur.

The formats for reporting waiting time and commuting time are attached and will be completed as appropriate in subsequent reports.

WAITING TIMES IN DISTRICT AND BRANCH OFFICES
QUARTERLY REPORT
__________QUARTER, 1986

Chart XI

NOTE: THIS INFORMATION WILL BE SUPPLIED IN THE FOLLOWING REPORT. DATA NOT AVAILABLE AT THIS TIME.

	National Average
I. Number of Visitors	
II. Average Waiting Time	
III. Number of Visitors Who Waited	
A. 0 - 5 Minutes	
B. 6 - 15 Minutes	
C. 16 - 30 Minutes	
D. 31 - 45 Minutes	
E. Over 60 Minutes	
IV. Number of Visitors Who Completed Applications for An SSN And Did Not Have To Be Interviewed (Not Included Above)	

Source and Study:

Brief Discussion of Statistical Methodology:

Every full-service SSA facility tracks the waiting time of office visitors once per week for 30 minutes at a time randomly selected for each site. In future reports statistical validity on a national level will be estimated based on the number of visitors.

Chart XII

COMMUTING TIMES
FOR CHANGED FACILITIES

NOTE: THIS INFORMATION WILL BE SUPPLIED IN THE EVENT OF ANY FACILITY CHANGE. NOT APPLICABLE FOR THIS REPORT.

FACILITY________________________________

DATE OF CHANGE_____________________________

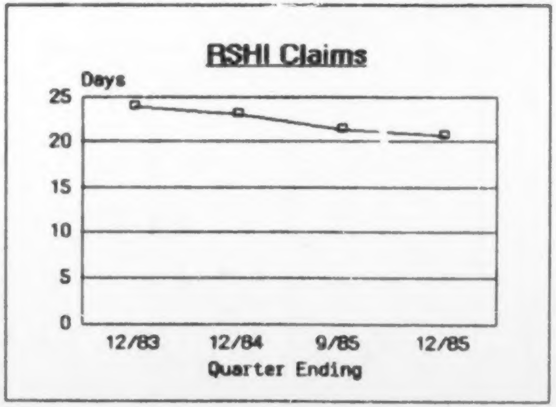
NATURE OF CHANGE___________________________

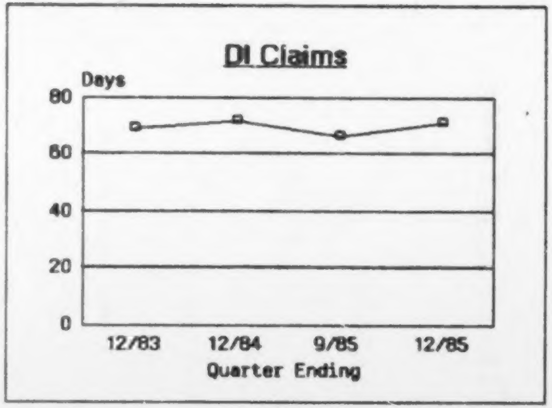
AVERAGE COMMUTING TIME PRIOR TO CHANGE____________

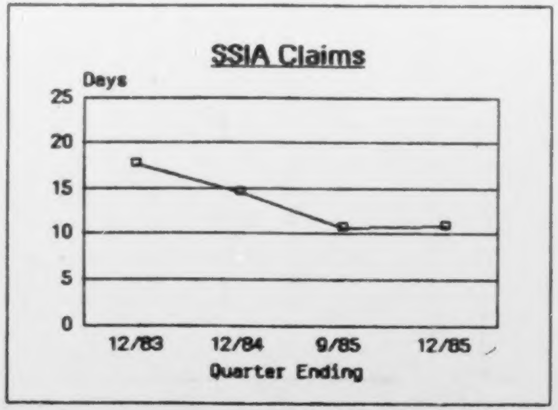
AVERAGE COMMUTING TIME AFTER CHANGE______________

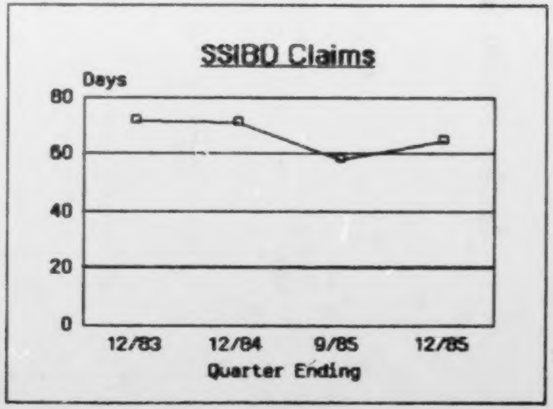
Source of Information and Methodology:

Mean National Processing Times

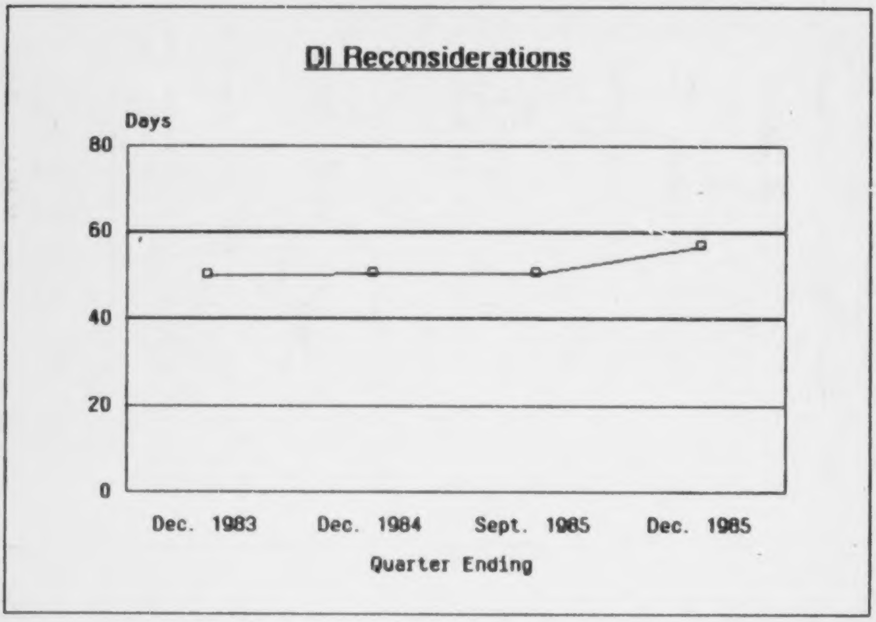

RSHI Claims

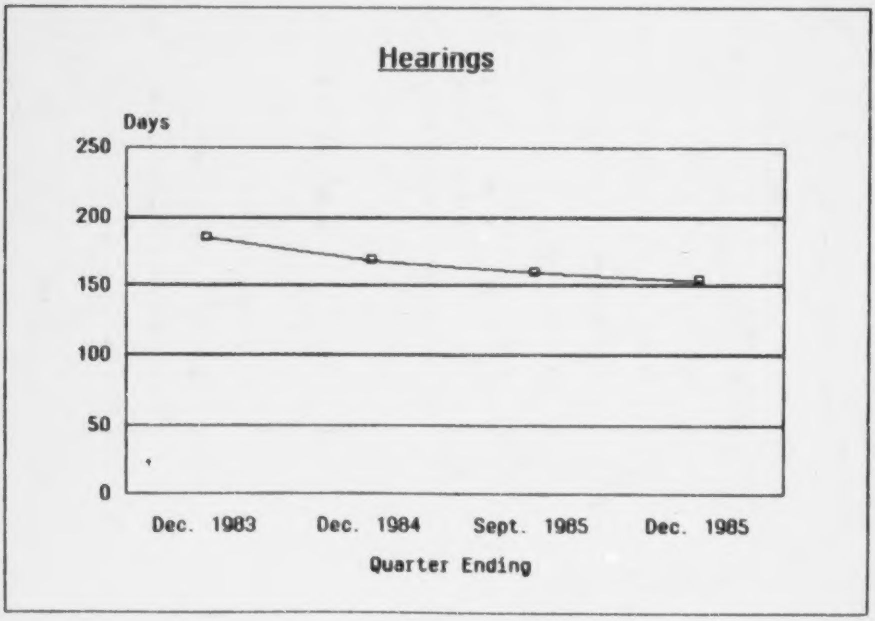

DI Claims


SSIA Claims

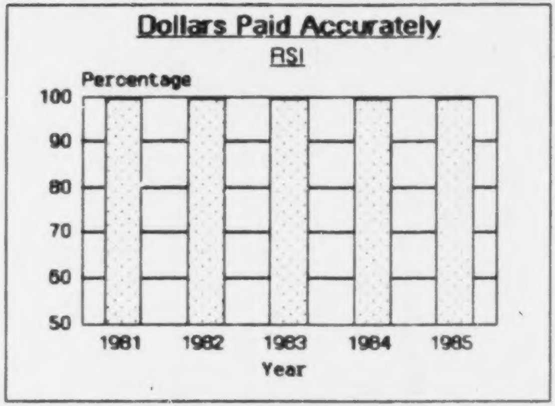

SSIBD Claims

Mean National Processing Times



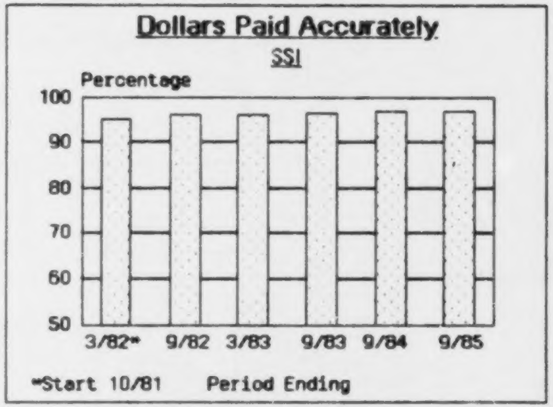


Accuracy



Dollars Paid Accurately

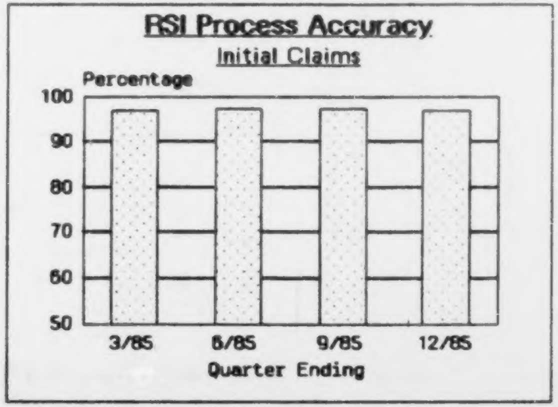
RSI



Dollars Paid Accurately

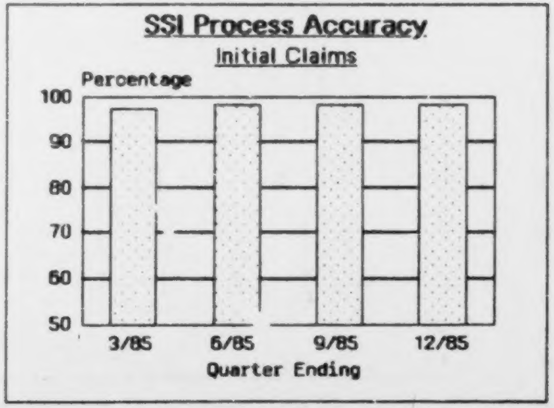
SSI

*Start 10/81



RSI Process Accuracy

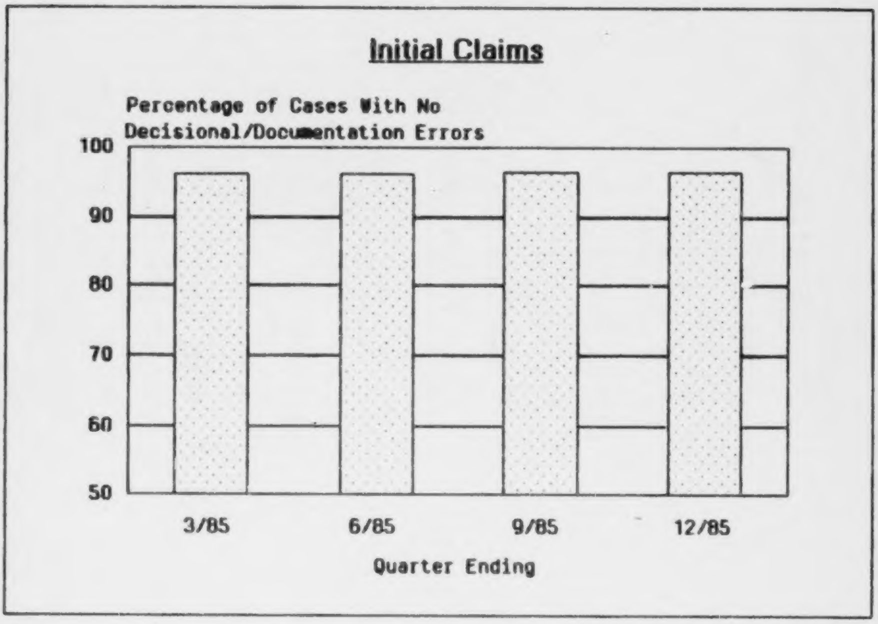
Initial Claims



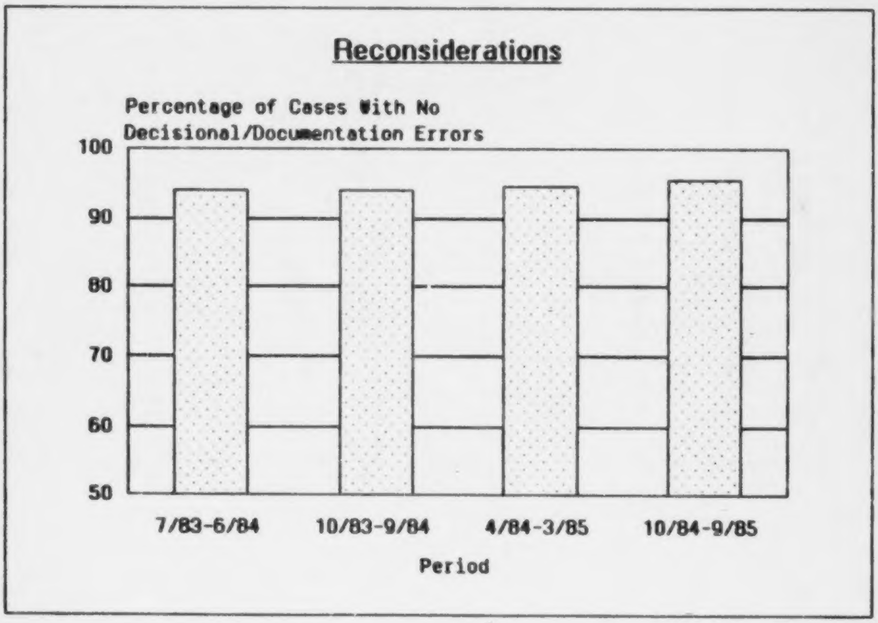
SSI Process Accuracy

Initial Claims

Disability Decisional Accuracy



Initial Claims



Reconsiderations

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
National Institutes of Health
National Cancer Institute

STATUS OF PRODUCTION AND TESTING OF HUMAN TUMOR NECROSIS FACTOR

Dr. Thomas E. Malone
Deputy Director, NIH

February 1986

STATUS OF PRODUCTION AND TESTING OF HUMAN TUMOR NECROSIS FACTOR

INTRODUCTION

In its report on the Fiscal Year 1986 budget for the Department of Health and Human Services, the Committee on Appropriations of the House stated in Report 99-289 on page 40:

> "Recently, there has been considerable publicity about tumor necrosis factor, or TNF, a protein which the body produces naturally, and which may kill cancer cells without harming normal cells. The committee requests that the Institute prepare and submit a report on the status of production and testing of this substance no later than January, 1986. The report should include information on foreign as well as domestic testing in animals and humans, efforts of the Institute to facilitate development and testing, and time schedules for clinical trials".

The following report has been prepared by the National Institutes of Health of the Department of Health and Human Services in response to this request.

BACKGROUND

In the early 1970s, during an investigation of the antitumor activity of normal serum, Dr. Lloyd Old and his colleagues, at Sloan-Kettering Institute for Cancer Research, discovered that serum from mice treated with Bacillus Calmette-Guerin followed by endotoxin could destroy certain mouse tumors. During the next 15 years, the Sloan-Kettering group and others throughout the United States, United Kingdom, Japan, and elsewhere sought to extract and purify the active component and to use it in treatment of animals and patients with cancer. The early research was hampered by inadequate amounts of pure natural material which was initially called tumor necrosis serum. When greater amounts of the purified material were available from mouse and rabbit sources, the compound became known as Tumor Necrosis Factor (TNF).

The early *in vitro* investigations using TNF derived from mouse or rabbit serum revealed that it was capable of killing a variety of tumor cells of mouse and human origin. Thus, there seemed to be no species restriction of TNF activity. Normal cells from the same animal species were spared. Unfortunately, only about 50 percent of tumor cell lines were sensitive to the killing effect of TNF. Even different human cell lines, with similar histology, varied in their sensitivity to TNF. In addition, certain mice carrying tumors were rendered tumor-free by the administration of TNF and few toxic side effects were seen. Due to limited supplies of relatively pure materials, only limited safety-testing in patients was carried out in the United States and in Japan. The promising results of these studies encouraged investigators to proceed with new attempts to generate large amounts of pure TNF for use in large-scale clinical trials.

BIOCHEMICAL PURIFICATION AND GENETIC ENGINEERING

Initially, TNF was characterized using the purification techniques of the 1970s. Evidence concerning the protein nature of the compound and the probable cellular source(s) was elucidated. By the beginning of this decade, the stage was set for the exact description of the active principle using the newest technologies in genetic engineering including amino acid sequencing and recombinant DNA technology. At least six different biotechnology companies, in association with various research institutions, approached this problem using slightly different methods; all have developed recombinant human TNF (rhTNF) with remarkable similarity to each other and considerable similarity to the natural product.

PRECLINICAL TESTING

The availability of rhTNF became the stimulus for expanded research efforts by commercial firms, as well as intramural NIH scientists and extramural scientists receiving NIH grants or contracts. RhTNF was shown to be similar in its actions to the natural mouse and rabbit products in virtually every respect. In addition, many other observations were made which were of particular relevance to ongoing and planned clinical trials. Some related to the ability of rhTNF to cause shock in experimental animals and to interact with other chemotherapeutic agents and recombinant human interferon; others described how rhTNF may stimulate the growth of some non-neoplastic cell lines or how resistance to the cytotoxic effects of TNF can occur on some tumor cell lines. Recently, a small working group of scientists at the National Cancer Institute was formed to coordinate intramural and extramural preclinical and clinical testing.

CLINICAL TRIALS

By February 1986, at least four of the commercial firms which successfully developed rhTNF have begun clinical testing in Japan and to a more limited extent in the United States. Additional trials sponsored by the National Cancer Institute, carried out by extramural and intramural clinical investigators, are about to begin within one month. The current trials are designed to determine the safest way to use rhTNF. Only after optimal dose, route and schedule of administration are defined, will it be possible to begin clinical trials for preliminary estimates of antitumor activity in well defined groups of cancer patients. Such trials will probably begin by late 1986 or early 1987. Few results of the early clinical testing have been released in this highly competitive field.

SUMMARY

The discovery of TNF 15 years ago has resulted in an increasing level of research activity. Progress was slow until techniques were available to generate large amounts of purified material. Subsequently, preclinical testing and safety testing in patients with cancer have progressed quite rapidly. Within the next two years, it should be possible to make initial estimates of the potential clinical utility of rhTNF.

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